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UNOFFICIAL TRANSCRIPT*
WASHINGTON STATE PHARMACY AND THERAPEUTICS COMMITTEE MEETING

February 21, 2007
Marriott Hotel Seatac
9:00am – 4:00pm

Committee in Attendance:
Angelo Ballasiotes, Pharm D
Jason Iltz, Pharm D
Daniel Lessler, MD (Chair)
T. Vyn Reese, M.D.
Patti Varley, ARNP
Kenneth Wiscomb, PA-C

Committee Absent:
Robert Bray, MD
Carol Cordy, MD (Vice Chair)
Alvin Goo, Pharm D
Janet Kelly, Pharm D

Dan Lessler:	Before we do introductions I just wanted to let people know that this afternoon Dr. Vyn Reese here on my right will be chairing the DUR portion of our meeting today as I need to leave early and Carol Cordy is actually out of town. So I appreciate you doing that, Vyn. I think what we'll do is go around and have introductions. Where do you want to begin, Jeff?
Jeff Graham:	Andre.
Andre Rossi:	My name is Andre Rossi. I'm a Director of Pharmacy for the Department of Correction.
Steve Harmon:	I'm Steve Harmon. I'm a medical consultant with HRSA.
Siri Childs:	I'm Siri Childs, Pharmacy Administrator with Washington Medicaid.
Jeff Thompson:	Jeff Thompson, Washington Medicaid.
Jaymie Mai:	Jaymie Mai with Labor and Industry.
Doug Tuman:	Doug Tuman, Pharmacy Consultant with L&I.
Alison Little:	Alison Little, Medical Director of the Drug Effectiveness Review Program.

* For copies of the official audio taped record of this meeting, please contact Regina Chacon at (206)521-2027 pdp@hca.wa.gov.

Jeff Graham: Jeff Graham, Consultant for the Prescription Drug Program, Health Care Authority.

Jason Iltz: Jason Iltz, Washington State P&T Committee Member.

Vyn Reese: Vyn Reese, P&T Committee Member and controlled medicine in geriatrics.

Dan Lessler: Dan Lessler, Chair of the P&T Committee, internal medicine.

Angelo Ballasiotes: Angelo Ballasiotes, committee member from Yakima.

Ken Wiscomb: Ken Wiscomb, committee member and practice family medicine in North Bend.

Patti Varley: Patti Varley, P&T Committee Member, Children's Hospital Child and Adolescent Psych.

Denise Santoyo: Denise Santoyo with the Health Care Authority.

Ray Hanley: Ray Hanley, Prescription Drug Program.

Duane Thurman: Duane Thurman with the Health Care Authority.

Elizabeth James: Elizabeth James, Pharmacy Consultant, Uniform Medical Plan.

Donna Sullivan: Donna Sullivan, Pharmacy Director, Uniform Medical Plan.

Regina Chacon: Regina chacon, Program Coordinator for the Prescription Drug Program.

Dan Lessler: Great. Thank you. Jeff, were there any other announcements that you wanted to make at this point?

Jeff Graham: No.

Dan Lessler: Okay. Gerald, are you there?

Gerald Gartlehner: I'm here.

Dan Lessler: Okay. We've got your PowerPoint projecting with the first slide. So you can just take it from there and just let us know when you want to change the slide.

Gerald Gartlehner: Okay. Great. Well, welcome again. I have [inaudible] the presentation in two parts. The first part is the actual update of the original drug class review on targeted immune modulators and then the second part is on the two new indications that we have added and those are ulcerated colitis and plaque psoriasis.

Slide 2 summarizes the included medications. We have added two new drugs, Abatacept and Rituximab. Those are administered intravenously and in the full report you can find the complete summary of all the drug specific properties.

Slide 3 should summarize the populations of each risk again. For this update we have added ulcerative colitis and plaque psoriasis, which are the new indications as I mentioned before.

Slide 4 and 5 just remind you of our [inaudible]. As always, our primary focus was in health outcome, which is functional capability or quality of life.

I would like to summarize slide 6. Slide 6 summarizes the findings for our update and overall we have included 44 new studies. Unfortunately, only two of them were head-to-head studies. Those were observational studies and unfortunately we still did not find any head-to-head RCTs for this drug class.

Slide 7 summarizes the new evidence on rheumatoid arthritis. As I mentioned, we found two new head-to-head prospective cohort studies comparing etanercept to infliximab and we also added one retrospective cohort study that did not meet our formal inclusion criteria but we thought it was still of interest. In addition, we found nine placebo-controlled trials on rheumatoid arthritis. We still do not have any head-to-head RCTs.

Slide 8 – what did these new studies add to the existing evidence? The two prospective cohort studies showed half the response rate of Etanercept than infliximab during the initial months of treatment, but then no differences thereafter. One study included contributed this different…primarily [inaudible] to obtain that. These findings are actually consistent with the non-randomized study that we already had in the original report, but then again all of these observational studies and they all have [inaudible]. So overall there was no difference in efficacy…passed on to the [inaudible]. The retrospective cohort study that we added did not find any differences between radiographic outcomes between etanercept and infliximab.

Slide 9 – in addition to the head-to-head study we found nine new placebo-controlled trials and these studies basically concern the channel of efficacy of targeted [inaudible] modulators for the treatment of rheumatoid arthritis. The effect size within these studies were large and there was [inaudible] across all trials.

Slide 10 – we added some of the new studies to our [inaudible] comparisons that we have conducted in the original [inaudible] report. [inaudible] did not change finding of the indirect comparisons. It still shows that anti-TNF drugs [inaudible] appear to be more [inaudible] than anakinra and we do not have any comparative evidence on abatacept or rituximab.

Slide 11 summarizes the results of these indirect comparisons graphically and as you can see all of these comparitants favor anti-TNF drugs over anakinra. Unfortunately, the evidence that we had was insufficient to have a [inaudible] we took [inaudible] after these indirect comparisons.

Slide 12 – juvenile rheumatoid arthritis we did not find any new evidence for juvenile rheumatoid arthritis. We still do not have any direct comparative evidence and [inaudible] of evidence [inaudible].

Slide 13 – the same situation for ankylosing spondylitis. We did not find any new evidence and we still do not have any comparative evidence for ankylosing spondylitis.

Slide 14 – for psoriatic arthritis we found two new trials. One on alefacept and one on adalimumab. The general [inaudible] of alefacept in this study was not very convincing. Only the ACR 20 response rate reached the 50/50 significant difference compared to placebo after 12 weeks and alefacept however is not FDA approved for the treatment of psoriatic arthritis.

Slide 15 – by comparison of the [inaudible] study showed significantly greater response rates on all ACR outcomes and overall the greatest comparative evidence for psoriatic arthritis is still poor. We still don't have any comparative evidence.

Slide 16 – we found one new study for Crohn's disease. This was four-week [inaudible] study of adalimumab. We [inaudible] showed significantly more remissions for adalimumab than for placebo and [inaudible] study point and adalimumab is also not FDA approved for the treatment of Crohn's disease. Once again the overall grade of the comparative evidence is still poor.

Slide 17 for adverse events we added 23 new studies. Most of them were observational studies.

On slide 18 in general these new studies did not change any of our inclusions. We still do not have any sound comparative evidence on the risk of individual [inaudible] modulators. The new studies basically confirm a general risk of these drugs [inaudible] malignancies and the only adverse events that we have slightly changed…where we have slightly changed our conclusion is on congestive heart failure.

Slide 19 – in the original report we had three RCTs on etanercept and infliximab and these RCTs were conducted in patients with congestive heart failure without rheumatic diseases and in these studies etanercept and infliximab were actually used to treat congestive heart failure and we felt that these studies showed a higher rate of mortality/morbidity with high doses of etanercept and infliximab. For the update now we added two new observational studies that were actually comparative in populations with rheumatoid arthritis and these new studies actually showed a lower incidence of congestive heart failure in patients on anti-TNF drugs. So we have classified congestive heart failure as meek evidence and we cannot really make any conclusions about it.

Slide 20 – we still do not have any long-term evidence on abatacept, alefacept, efalizumab, and rituximab and the overall rate of the comparative evidence is still poor.

Slide 21 – for subgroups to be added six new studies, four observational studies and two database(?) analysis and these studies did not lead to any changes in [inaudible] and again the overall rate of [inaudible] is still in the works.

Slide 22 – this is the second part of the presentation, but we've added two new indications and one of our new indications was ulcerative colitis. Concurrent in only infliximab is FDA approved for the treatment of ulcerative colitis. In summary, we did not find any head-to-head trials on [inaudible] modulators for the treatment of ulcerative colitis.

Slide 23 – we found some evidence of a general efficacy and so those were three placebo-controlled trials that provide fair evidence of the general efficacy of infliximab. Patients in these trials all suffered from moderate to severe ulcerative colitis and they all failed conventional treatment. Study durations were between 12 and 54 weeks. In all three trials infliximab was significantly more efficacious than placebo and treatment effects generally were rather large.

Slide 24, for example, in one study the rate of colectomies was significantly lower in the infliximab group than in the placebo group and likewise responding to a significantly higher infliximab treatment. What was remarkable was the drug

[inaudible] in the infliximab groups were relatively high. They ranged from 19% to 40%.

Slide 25 – we did not find any evidence on all the other cognitive modulators and therefore the overall grade of the comparative evidence is poor.

Slide 26 – the second new indication was plaque psoriasis. Once again we did not find any advanced studies that define psoriasis. Existing evidence from placebo-controlled trials was unfortunately insufficient for [inaudible] comparisons.

Slide 27 – overall we found 12 placebo-controlled trials and currently one alefacept, efalizumab, etanercept and infliximab are FDA approved for the treatment of plaque psoriasis.

Slide 28 – these efficacy studies have study durations that range from 10 to 24 weeks. They enroll patients with moderate to severe plaque psoriasis who have at least partially failed conventional treatment.

Slide 29 – all of these efficacy studies provide good [inaudible] that TIMs drugs are highly efficacious for the treatment of plaque psoriasis. Treatment effects were large and [inaudible] study [inaudible] response rates ranged between 30% and 80%. The evidence as I said is insufficient to conduct either a comparison and therefore the overall grade of the comparative evidence is still poor.

Slide 30 – in summary we still do not have a single double-blind [inaudible] comparing to [inaudible] modulator.

Slide 31 – except for the indirect comparisons [inaudible] the greater efficacy of [inaudible] drugs compared with the [inaudible] for the treatment of rheumatoid arthritis all the other indications…the evidence is insufficient to draw any conclusions about the comparative efficacy or effectiveness.

Slide 32 – the evidence is also insufficient to draw conclusions about the comparative safety and tolerability and rare but severe adverse events such as serious infections, malignancies, immune [inaudible] such as [inaudible] they are the issue of all of the targeted immune modulators and it really leaves no other [inaudible] long-term evidence to really make a conclusion about the long-term [inaudible] ratio of the drug.

So this is the last slide. If you have any questions, please go ahead.

Dan Lessler: Thank you, Gerald. Actually, at this point I was going to open it up to P&T committee members if they had any questions or Gerald's presentation here for him. Okay. Gerald, are you available to stay on the phone for about another 15 to 20 minutes or so? We're going to take stakeholder comment and sometimes there are questions that arise in the context of those comments that it's helpful to have you available.

Gerald Gartlehner: Absolutely.

Dan Lessler: That would be great. Okay. So I have four people signed up so far. If you're planning to speak you should have signed up on the sign up sheet here. I ask that people please limit their questions to three minutes and if you could also please identify if you're here representing a company or if you're sponsored by a company we'd appreciate that as well. And I will be strict in holding people to the three-minute time limit. First on the list is Dr. Greg Miller.

Greg Miller: Good morning. My name is Greg Miller. I'm a medical science [inaudible] at Bristol-Myers Squibb. I would just like to thank the committee for allowing me to provide some updated information on Orencia. Orencia is a co-stimulatory modulator indicated for moderately to severely active rheumatoid arthritis after an inadequate response to at least one dimer.

It can be used as monotherapy or combined with dimers other than TNF antagonists and is not recommended to be given with other biologic dimers. I'd like to emphasize that Orencia works by a novel mechanism of action namely by inhibiting the second signal required for full T-cell activation resulting in a down regulation of the immune response leading to decreased activation of effector cells and lower levels of inflammatory chemokines. This results in improvement in signs and symptoms and rheumatoid arthritis and significant slowing of radiographic progression of disease.

Orencia was approved by the FDA in December 2005 and became commercially available in February 2006. As investigations continue data is continually being generated. Since the current version of the Oregon report was published two sets of important data have been presented. The report contains data from the aim and attain Phase III trials. Two of the pivotal trials demonstrating Orencia's efficacy and safety in rheumatoid arthritis after an inadequate response to methotrexate, a traditional dimer, and after an inadequate response to one or more anti TNF agents. These trials both have open label, long-term extension phases, which demonstrate durability of the efficacy response in rheumatoid arthritis patients with no change in dose or dosing interval over time and without any new safety signals. In fact, safety data from the long-term extension phases of these trials as well as safety data from subsequent trials with Orencia correspond well to the integrated safety summary submitted to the FDA in the approval application.

Additionally, a very interesting trial was presented at this past November's American College of Rheumatology annual meeting. This trial, part of BMS's global registration efforts compares Abatacept to placebo and Infliximab to placebo. While not a head-to-head comparison it is an evaluation of both efficacy and safety of Abatacept and Infliximab in the same patient population at the same time. This trial demonstrated that both agents produced significantly better efficacy when compared to placebo with durability of affect through the one year of the trial. However, there were remarkable differences in the safety profile of Orencia and Infliximab with Orencia results in approximately 50% fewer serious adverse events and about 50% sewer subjects discontinuing the trial due to adverse events in the Orencia group compared to those in the Infliximab group. As both these agents are given by infusion the incidents of acute infusional events was examined and showed an incident rate of 7.1% with Orencia compared to 24.8% of subjects receiving Infliximab, more than three times higher.

Once again I'd like to thank the committee for the time to speak and would be happy to provide details of these data if the committee desires. Thank you.

Dan Lessler: Thank you. Any questions? Thanks. Gerald, did you have any comment?

Gerald Gartlehner: Uh, no, I don't.

Dan Lessler: Okay. Thanks. Next is Dr. Carrie Johnson.

Carrie Johnson: Hello. Thank you for the opportunity today to speak on behalf on Enbrel. I'm Carrie Johnson and I'm a regional medical liaison with Amgen. In the next few minutes I'll

highlight five of the key attributes of Enbrel. The first being mechanism of action. It's the only fully human soluble TNF receptor [inaudible] antibody and as such has not been shown to induce neutralizing antibodies or to cause cell [inaudible]. Number two is the indications. Enbrel has the broadest scope of indications crossing both rheumatology and dermatology. These indications include RA, psoriatic arthritis, psoriasis, ankylosing spondylitis and a pediatric indication for juvenile rheumatoid arthritis. The pediatric indication differentiates Enbrel and may be important for a plan such as yours for the pediatric population. It may be relatively large.

Enbrel has been studied in patients down to two years of age and now has sustained efficacy and safety data out to five years in this pediatric JRA population.

Efficacy – Enbrel has demonstrated now sustained clinical responses in patients with RA out to nine years at a stable dose. Enbrel in combination with methotrexate has now shown sustained halting of radiographic progression out to three years. There are fully published safety and efficacy data for this product out to seven years. This is the only product with such long-term data available.

Dosing – Enbrel provides predictable dosing. It has not been shown to cause a formation of neutralizing antibodies, which may affect efficacy and maintenance of response over time. Additionally, there is no labeling allowing for increases in dose of Enbrel.

Safety – Enbrel is the only one in the class with fully published safety data out seven years. Unlike other TNF antagonists Enbrel has no black box warnings and the only adverse event seen more often in treated versus untreated patients has been and continues to be injection site reactions. Additionally, no testing pre or post initiation or routine laboratory monitoring specific to Enbrel is required. Rates of serious adverse events and serious infections have remained low and stable over time over the past nine years and not significantly different from placebo or methotrexate.

In conclusion, Enbrel is unique among TNF antagonists. Enbrel has over 14 years of collective clinical trial experience in over 450,000 patients worldwide across indications. We've just totaled over our one millionth year of patient exposure and rates of serious adverse events have remained low and stable over time and with the exception of injection site reactions not significantly different from placebo or methotrexate. Enbrel has a pediatric indication, no black box warnings, predictable dosing and published sustained long-term safety and efficacy data. Thank you.

Dan Lessler: Thank you. Any questions or comments? Thanks. Likewise, Gerald, I don't know if you have any comments?

Gerald Gartlehner: Uh, no.

Dan Lessler: Thanks. Next is Dr. Robert Ettlinger.

Robert Ettlinger: Good morning members of the committee. I'm Dr. Robert Ettlinger. I'm a rheumatologist in private practice. I've been in Tacoma almost 30 years now and while I've been on the Speakers Bureau of Humira, Enbrel, Orencia and Rituxan I'm here today on my own accord to ask that you include Humira on the Medicaid formulary so that rheumatologists and other people treating rheumatic diseases can have the choice of using Humira for their patients with potentially crippling disease.

Over the 30 years I've been in practice I've seen the entire landscape of treating these once almost always crippling and functional disabling diseases such as rheumatoid arthritis and psoriatic arthritis and ankylosing spondylitis progress to the point of helplessness, but with the advent of biologic therapies such as these we now can offer patients a reasonable chance at remission and an almost certain chance of response. And yet in spite of all of these advances we still cannot determine which patient will respond to which drug. There is no test to tell us that this is a Humira responder or an Enbrel responder, a Rituxan or an Orencia responder. We still have to use trial and error and in spite of the great progress we've made as many as 25% of patients will not respond to one particular drug and another 25% will gradually lose that response. And so therefore we need the choices of other drugs such as Humira to replace the initial drug utilized or perhaps to start with.

Some advantages that Humira may have over other therapies is its convenience of one injection every two weeks and the lack of a necessity to use it with methotrexate which may be contraindicated in patients such is the case with Remicade.

Thank you very much for the opportunity to address you and I hope you'll give me and other practitioners the option for a wider choice in Medicaid patients being treated for severe rheumatic disease. Thank you very much.

Dan Lessler: Thank you. Any questions? Gerald?

Gerald Gartlehner: No.

Dan Lessler: I was going to ask earlier if you could just…I know in the report there was mention as well of sort of individualized response to the different agents and I was wondering if you had any comment on that?

Gerald Gartlehner: Oh, um, it is a good point. [inaudible] of patients do not respond to the drug and it is not foreseeable who will respond and who will not respond. One of the major differences that we point out in the report as well and is [inaudible] every other week and Anakinra is daily and this might make a great difference in the appearance of the drug although we do not have any data that confers such data. Overall, as mentioned, the data is still saying that we cannot really tell anything about the comparative efficacy and whether one is better than another in the TNF drugs. So they appear to be similar and the differences in the administration schedule primarily.

Dan Lessler: Thank you. Thanks. Next is

Woman: …and I'm with Abbott Laboratories. Thank you for allowing me to address you this morning. I just wanted to briefly highlight several key points with Humira. Humira is the first fully human monoclonal antibody against TNF [inaudible]. It does not bind TNF data or lymphotoxin. It has been on the market for a little over four years, but has six years worth of clinical trial efficacy data and over 160,000 patients have been treated with Humira globally.

Humira has shown to have rapid onset of action significantly reducing the signs and symptoms of RA within just one week. It improves physical function and inhibits radiographic progression of the disease. It is also indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. Now more recently it's been used to reduce the signs and symptoms of active arthritis in psoriatic arthritis patients where almost half of the patients achieved a posi 90 score, which is a 90% improvement of their skin lesions in conjunction with over 60% of patients achieving

an ACR 20 response at one year. Now results such as this has only been seen with anti-TNF monoclonal antibodies in PSA.

Now in RA Humira can be used alone or in combination with methotrexate or other DMARDs given 40 mg as a sub Q injection every other week with or without an auto inject pen. Now Humira can be given weekly in patients who cannot tolerate methotrexate or other DMARDs and have had an adequate trial of standard dosing. However, there is conflicting evidence with a benefit of higher dosing in clinical trial data. In a patient preference study on overall administration conducted by the Rheumatology Research International 73% of patients preferred Humira compared to 25% with Remicade and 2% with Enbrel.

For safety, as of April 2005 Humira had over 10,000 patients in global clinical trials where serious infection, tuberculosis and lymphoma rates were well within the range of other documented anti TNF and biologic naïve RA patient incident data. Last August Humira filed for an indication in the treatment of Crohn's disease and was granted an expedited review by the FDA.

So in conclusion I just want to highlight Humira has an abundance of both clinical trial efficacy and safety data and also has a benefit of ease of administration and other week dosing. Thank you.

Dan Lessler: Thank you. Any questions or comments? No? Gerald, anything else?

Gerald Gartlehner: No, not from my side.

Dan Lessler: Let me just ask before we let you go here, Gerald, whether there are any other questions here for you from P&T members and I think there are.

Vyn Reese: Gerald, hi, it's Dr. Reese. I have a question about Crohn's disease. Now Humira now has the indication for Crohn's disease as well as Infliximab. Is that correct?

Gerald Gartlehner: Could you repeat the question, please?

Vyn Reese: The question is Humira has an indication for Crohn's disease as does Infliximab? Or is it still just on expedited review?

Gerald Gartlehner: Yeah, I think you're right. Humira does not have an indication for ulcerative colitis, but I think you're right for Crohn's disease.

Vyn Reese: Okay. Thank you.

Jeff Graham: Dan, this is Jeff Graham. I think we just discussed this as staff this morning and we think that indication has not been given yet, but could be pending very soon.

Dan Lessler: Okay. Thanks.

Patti Varley: This is Patti Varley, Gerald. I just want to clarify what the data says in regard to the pediatric population?

Gerald Gartlehner: Well, the data [inaudible] pediatric population is not very good. There's only one RCT on the [inaudible]. This RCT has some [inaudible] issues. The patients were highly selected. Everybody…about 25% had a active running phase about 25 [inaudible]. Only patients who actually responded to the [inaudible] in this active running phase

were then concluded in the actual RCT and this is the only RCT that we have. There are no other RCTs. There are a couple of open label studies on Adalimumab and Infliximab, but they are not convincing to improve any efficacy. So in summary the evidence is very poor. Even the one RCT that we have on Adalimumab is very poor. The FDA reviewed the statistics of this RCT and the FDA located some issues with recommendation and they concluded that only three patients…in worst case scenario switching three patients from one group to the other could have led to a non statistical finding. So unfortunately the data is very poor for [inaudible].

Patti Varley: Thank you.

Dan Lessler: Thanks. Any other questions for Gerald? No? Gerald, thank you very much. This was an excellent presentation and I appreciate your taking time this morning to spend time with us.

Gerald Gartlehner: Okay. Thank you.

Dan Lessler: Take care. Bye, bye.

Gerald Gartlehner: Bye.

Dan Lessler: So I think at this point what I would ask committee members to do is to turn to the prior motion, which I think for us is sometimes a good place to get started although there are additional agents that are being considered today beyond that, which were considered when we last discussed this particular topic. So people can take a look there and I think it…Jeff, did you have a comment?

Jeff Graham: Well, I think the template mentions the new drugs and…

Dan Lessler: Right. I just wanted people to be aware that there are new drugs that are being considered this time so that they need to…people need to be keeping that in mind when they just review the previous motion that passed on this about a year ago. And I think at this point I would ask if just by way of getting committee member's thoughts about the drug class what we've heard today…yeah?

Siri Childs: This is Siri Childs, Washington Medicaid and I would just like to remind the committee that all drugs in this drug class whether they are preferred or non preferred are on EPA (Expedited Prior Authorization) for their FDA labeling.

Dan Lessler: Thanks. So I guess I would ask if any committee members would want to comment at this point in terms of what we've heard and perhaps a general sense of where we might go with this?

Patti Varley: This is Patti Varley. I'm just turning to the committee to see if I'm thinking of this in the way I think is correct and that is that the evidence still talks about the fact that there is no evidence that one is outstanding over another, but there is evidence that individuals respond very differently. So what I didn't see in the data, and I don't know if anybody knows about this, is there a way to look at the list, have a patient and predict which one they might respond to or not? And if not then it seems like the trials would occur no matter what and no matter what's on the list they can get it in EPA if it's for Crohn's and it's been approved for Crohn's or it's for pediatrics and it's approved for pediatrics. But also if they try and fail whatever's on the list and that doesn't work they could DAW something as well. And I just want to make sure my logic is correct.

Dan Lessler: I was going to say before passing this to Vyn that I think your logic is correct and from what I understood of the presentation and from my reading there's no way to predict individually who will respond initially.

Vyn Reese: This is Dr. Reese. I think another thing we need to take into consideration is the administration of the drugs. I mean the drugs that are infused have a higher rate of reactions in the drugs that are injected sub Q tenuously. So that's one plus for the sub Q tenuous drugs. So I think that's something we need to consider, but that again if a drug that's given sub Q tenuously isn't working then obviously an infused drug will be used as well. So I think we need to include in our next motion to include the two new drugs that have indications for RA.

Dan Lessler: Thanks. Other comments or observations? So having heard the presentation and I think the points that Patti and Vyn made I'm wondering if somebody would be willing to put forth a motion? That would be great.

Vyn Reese: This is Dr. Reese. This is my motion from last…I gave the motion last year so I'll try this year with including the newer agents. After considering the evidence of safety, efficacy, effectiveness and special populations for the use of targeted immune modulators for the treatment of immunologic conditions for which they have FDA indications, I move that etanercept, adalimumab, infliximab, abatacept and rituximab are safe and efficacious. No other Targeted Immune Modulator medication is associated with fewer adverse events in special populations. Now I was hoping I could change this, but [inaudible] aside. But still infliximab must be included for the treatment of Crohn's disease in addition to a self-administered agent for other indications. These medications cannot be subject to therapeutic interchange in the Washington Preferred Drug List.

Dan Lessler: So it's essentially the same motion as previously with the addition of abatacept and rituximab. Right? Siri?

Siri Childs: You may also want to consider ulcerative colitis.

Dan Lessler: For infliximab? Yeah, that's right.

Man: [inaudible]

Dan Lessler: Okay. Is there a second?

Man: [inaudible]

Dan Lessler: Ken seconds. Any further comment or discussion? Siri?

Siri Childs: I don't know if you need to include this in the motion, but just remember that they are still on APA for their overall indications whether they are preferred or non preferred.

Patti Varley: This is Patti Varley. I'm assuming that means that for instance ones that are FDA approved for juvenile are covered no matter what. So I don't have to have that be a separate statement in there. Is that correct?

Siri Childs: Well, Enbrel currently is the only one that is FDA approved for juvenile rheumatoid arthritis. So you may want to specify that. I don't know how the actual decision will pan out, but if you're looking for that that should probably be specified.

Patti Varley: So for me that would be important to make sure it was in there like Crohn's disease and ulcerative colitis. This is Patti Varley.

Vyn Reese: I think it's in the motion. It's in addition to self-administered agent for other indications. So I think that is in there basically. The only one is Enbrel for juvenile RA. We could add that if you wanted, but it's sort of already indirectly in there.

Dan Lessler: Patti?

Patti Varley: I guess I would prefer direct because things change.

Dan Lessler: Okay. So would you take that as a friendly amendment.

Woman: I missed what you said so you'll have to repeat what you want added.

Dan Lessler: I think specifying that Enbrel would be available for…

Vyn Reese: So after the statement on Crohn's disease and ulcerative colitis, etanercept must be included for juvenile rheumatoid arthritis…for the indication of juvenile rheumatoid arthritis.

Dan Lessler: Okay. Any other discussions? So maybe, Vyn, I'll have you read it one more time and then we can vote. Thanks.

Vyn Reese: After considering the evidence of safety, efficacy, effectiveness and special populations for the use of targeted immune modulators for the treatment of immunologic conditions for which they have FDA indications, I move that etanercept, adalimumab, abatacept, rituximab and infliximab are safe and efficacious. No other Targeted Immune Modulator medication is associated with fewer adverse events in special populations. Infliximab must be included for the treatment of Crohn's disease and ulcerative colitis in addition to a self-administered agent for other indications. Etanercept must be included for the treatment of juvenile rheumatoid arthritis. These medications cannot be subject to therapeutic interchange in the Washington Preferred Drug List.

Dan Lessler: That was seconded by Ken. So why don't we go ahead and vote. All those in favor say, "I."

Group: I.

Dan Lessler: Opposed, same sign. Okay. The motion carries. Thanks. Jeff, we're thinking about 10 of 10:00. I didn't know whether you wanted to extend the break here or how long you thought the subsequent discussion would go or what you'd like to do. Okay. So we're going to adjourn until 10:15 and we'll convene at that time. Thanks.

…the next hour and a half or a bit more to sort of review where things are at with the current DERP process and talk about where they are headed. I think Jeff Graham was going to…was going to lead off and then I think, Jeff, I'll let you formally introduce Alison as well. Thanks.

Jeff Graham: We're going to go over where we've been and we're going in our project here, the Washington State Prescription Drug Project and our contract with the Center for Evidence Based Policy and Oregon Health and Sciences University. Some of us have

lived through this now for…actually, I just realized I'm almost finishing my fifth year consulting on this project. It doesn't seem possible, but it is. And so let's have the next slide here.

We started in 2002. Actually, the state convened a group of people in 2001 who made some of these recommendations that we have followed and what we have actually implemented, but in 2002 the health care authority led the three agencies, which was DSHS, which is the Medicaid part; Labor and Industries, which is our worker's compensation in this state; and the Health Care Authority and particularly the Uniform Medical Plan, which is the public employees PPO plan, to come together and work together to purchase drugs. During that time Oregon had started doing these evidence based reviews for drug classes through their…I never remember. Is it the health services? The Health Resources Commission and some of our folks here in Washington got to talking with them and saying, "Well, maybe we could join in with that and the next thing we knew was that Idaho was joining in too. So actually in the fall of 2002 we met with the folks from Oregon and Idaho to see if we couldn't work together in doing drug class reviews. And actually at that time 12 drug class reviews were being done. Next slide.

And those classes are…and they are listed here. Some of you were involved very early in looking at those classes and some of them later, but these were done and I think accomplished the initial reviews sometimes in 2003, but this is quite an undertaking. Next slide.

So in Washington we elected to start this process using the Washington Medicaid Drug Utilization Education Committee, which we have two members…three members from that committee are here today who are now on our P&T Committee. We did a very rapid review. I think we were meeting monthly and actually got through all 12 classes in that year. So it was a very, very rapid review and decisions made about a preferred drug list.

During this time the legislature wanted to develop a little bit more, I guess, support for us you might say and actually passed a law, which was senate bill 6088, which did establish what we call evidence based prescription drug list and we call it our evidence based prescription drug program and said that agencies could come together to join this and I don't believe that specific agencies were named, but since our three agencies were working together we are included in this and other agencies could come into this process. So we developed our pharmacy and therapeutic committee and as you recall our first meeting was in October of 2003. At that meeting I don't believe we reviewed any drug classes, but we did…we were very helpful in developing the working rules of this committee and made a major difference in how we operate. At the same time and I think the next slide…

And then Oregon went ahead and developed what they call the Center for Evidence Based Policy and that agency within the OHSU then developed this project what we call DERP or Drug Effectiveness Review Project and contracted with the OHSU Evidence Based Practice Center to do the reviews for us. And we had our first meeting in October of 2003. So at the same time as we were having our first meeting of the P&T Committee, the first meeting of DERP happened with the participating organizations. And I believe the next slide gives the participating organizations.

We call this now DERP 1 and this was a three-year contract that we had and not all states came in at the same time, but they finally all signed on. New York was one of the first ones to be there and one of the last ones to sign on, but we did have them. We

had…these are not all state Medicaid agencies and of course Washington is a three agency. Most of the rest are the Medicaid agencies. California Health Care Foundation was one of the only really non-profit private organizations that signed up and the Canadian Coordinating Office on Health Technology Assessment, which the name has been changed, but anyway they also signed in and have remained…you'll see as we go on that there are 17 here and when Alison talks there will be three that are no longer there and you'll be able to pick those up pretty easily.

DERP 2 has 14 of these original 17 still participating. So any questions? Let's see the next slide.

Oh yes, and then we reviewed 16 more classes and I wanted you to see how much work you've done since we started. In fact, you know, this committee has done two more classes that were not DERP projects. We did the nasal corticosteroids and macrolides so it's been quite a bit undertaking and I think…so we've had a total of 28 classes done by the Evidence Based Practice Center and we actually have two coming out yet that are under DERP 1 and that's interferons for Hepatitis C and the drugs for multiple sclerosis. So those will be completed most likely this summer when we will probably review those. I think that's all we have for this part.

Now Alison Little will do the presentation about DERP 2. Alison is the Medical Director for the Center for Evidence Based Policy. Some of you had met John Santa who has been the previous Medical Director, but Alison came in I think last spring and is doing an excellent job. She is the editor of all of these nice several page reviews for us, the P&T Committee briefs. So we really appreciate that.

Alison Little: Okay. Next slide, please. DERP really started its origins back in the year 2000 when the Oregon State Medicaid Program saw a 60% increase in their drug spend. Of course they were in the midst of a serious budget short fall and in response to that they passed senate bill 30. That instructed the state to develop a preferred drug list and they were specific in saying that they should consider effectiveness first and then in the case the drugs were found to be effective then cost could be considered. In order to do this the state entered into a collaboration with the Oregon Evidence Based Practice Center and developed the first four reports. They shared these with Washington and Idaho and then Jeff gave you the history behind what happened next for DERP 1. Next slide, please.

So drug effectiveness review project were a self-governing collaboration of organizations that obtained and synthesized global evidence on the comparative effectiveness, safety and effects on subpopulations of drugs within classes. And we support policy makers in using that evidence to inform policy in local decision making. Next slide.

This is what the project looks like. The states and non profits form the governance group. They are responsible for making all policy decisions for deciding which classes to review and in conjunction with the EPC in developing the time line. They are supported by the Center for Evidence Based Policy who I work for and we enter in contracts with the Oregon Evidence Practice Center who does all the systematic reviews or contracts them out. Next slide.

A little closer look at those last two entities. Center for Evidence Based Policy – our mission is to address policy challenges by applying the best available evidence through self governing communities of interest. In addition to providing support one of our main tasks is facilitating communication between the governance group, the EPC and

the industry. The Oregon Evidence Based Practice Center is a federally designated research center housed at OHSU that uses state-of-the-art methods for conducting systematic reviews. Again, if they don't perform the reviews themselves they subcontract them out to another federally designated EPC and supervised network. Next slide.

So here are the DERP 2 participating organizations now. You can pick them out. The folks who are no longer participating are the two California entities and Alaska. Everyone else is still there although Canada has changed their name. Next slide.

So I know you're all familiar with what a systematic review looks like, but I'll just review it briefly. They start with key questions that are chosen by the participants. Those are sent out for public comment and at times revised in response to that comment. The inclusion and exclusion criteria are specified and then a global data search is performed. The data that's retrieved is analyzed for quality and all the good or fair quality evidence is then synthesized into a draft report. That draft report is presented to the participants and after their approval then it's submitted first to peer review and then again to public comment. Those public comments are again brought back to the governance group, incorporated into the report as needed and a final report is produced. That usually includes a full text report, as well as a separate report of evidence tables, a PowerPoint presentation, often times an executive summary and since August of last year a P&T Committee brief. Next slide.

The reports are used in different ways by different states. North Carolina for example uses them strictly for provider and consumer education. Idaho as an example uses them to augment their P&T Committee information. Washington, of course, uses them as the primary P&T Committee information base and Canada uses them to support other levels of government. Next slide.

So, what are the deliverables for DERP 2? We anticipate that there will be eight original reports, 20 to 25 update reports or journal article equivalence. We'll do annual scans of each report topic that I'll talk a little bit more about later and then…

Alison Little: …evaluated based on their size. And there are different price tags for different sizes. The budget is built on the idea that there will be four medium, two small and two large reports. However, if it ends up that none of the reports are large, there will be money left over either to do another original report or more updates. Also, if the participants decide that they really don't need eight original reports, they can take some of those funds and do more updates with them. So there is quite a bit of variability in there.

Because of the differences in size, there is also differences in timelines varying from 32 weeks for a small report to 48 weeks for a large one. Updates also vary any where from 28 to 48 weeks. Next slide.

So how are these original reports selected? Because they had so few options in DERP 2, they wanted to make sure they chose wisely and so they developed a more formalized process of choosing original reports. It begins with soliciting five topics from every participant. Those are sent to the center. We collate and rank them based on frequency of voting and then we take the top ten. Of those top ten we'll develop a briefing paper with the help of both the states and the EPC to look at such things as disease burden, alternative interventions, clinical impact, budget impact, economic impact, what evidence is available, marketing strategies and any policy issues that the states have. Then a final vote is taken at the face-to-face governance meeting. Next slide.

Three topics have been selected so far: Neuropathic pain is due in September of 2007, drugs for constipation has a similar expected completion date and combination products for diabetes and hyperlipidemia is expected November of 2007. Next slide.

Updates also have a more formalized process for being selected at this time. We will be performing an annual scan of each class and this includes a literature search of Medline only for new randomized control trials since the date of the last report. We will present all those abstracts as well as identifying any new drugs in the class, any new indications and any new safety alerts. Those are presented during governance calls and a vote is taken. Next slide.

So far eight classes have been scanned and we have had pretty much a splits on whether or not to update. The classes that have been chosen to update are ADHD, which was chosen because of a new drug in the class. Atypical antipsychotics, there was a very large volume of literature found that was new. Beta-blockers, there was a new preparation. And Estrogens, there was new safety information. Classes that were chosen not to update: Calcium channel blockers, newer anti-emetics, newer drugs for insomnia and statins. And there are two sample scans in your folders, beta-blockers and calcium channel blockers for you to take a look at. I think that's my last slide.

Dan Lessler: Thanks. Are there questions for Jeff or Alison regarding the process? Actually, just maybe for Alison, just maybe a point of clarification. My understanding is initially when the process began the reviews were limited to randomized control trials. And so more observational type data, which can speak oftentimes more to safety was not included. But now that the scans include, or have broadened out to include observational studies as well as that. Is that correct?

Alison Little: I think it depends on the drug class. Certainly if they're trying to get effectiveness rather than efficacy data, there's a tendency to include more observational studies. And they've always included them for the safety information.

Dan Lessler: Yeah, okay.

Patti Varley: This is Patti Varley and I'll say this for Carol. And that is that she, I think, always brings us back to the question of quality of life values as well as medication efficacy. And I'm wondering if that's part of the plan is to look at quality of life outcomes for patients?

Alison Little: I would say that that…it seems that the participants are requesting that more frequently. For example beta-agonists, there was much more focus on quality of life issues and effectiveness. But, again, it's going to depend on the drug class. And, again, the decisions are strictly those of the governance group.

Dan Lessler: I was wondering if you could comment on why California dropped out?

Alison Little: You know, it was before my time. I honestly don't know. I know that Mark Gibson had conversations with them. But I think he would say they need to speak for themselves.

Dan Lessler: Okay. And for those who remain, obviously there's a sense of no matter how they use the information of added value, I'm wondering, you know, what the range of that added value is? It's interesting to see…just curious to see that. I think North Carolina just uses these informationally. I mean, I'm just curious whether they've done any

kind of evaluation whether just providing information has had any impact on prescribing?

Alison Little: Yeah, I don't believe they have. I think they have a difficult political situation there, which prevents them from using them, as most of the other states do. And why they choose to continue to participate, I really don't know.

Dan Lessler: And then, Jeff, I was just wondering in terms of this state if you could just comment on the status of the current process that was set up under, sort of legislatively, directed where it stands within the state, if there are any thoughts or, you know, anticipated changes or discussions and so forth?

Jeff Graham: I probably should have Duane answer this, but I'll make a few comments. My impression is that we're seen as a very successful program. That we do follow evidence-based materials and reviews, that our process is quite transparent. The only time that really we're behind closed doors is when we're talking about financial issues and that it's not something…it's proprietary and actually I don't ever see financial issues. All I see is weighted numbers, so I don't know what the dollars mean at all. So I think we're seen as using a process that is pretty open. And we're seen as a successful project within the state. And I don't know, Duane could probably say if there's any challenges to us right now, but basically we're not completely hands…we're not up too far, but I think sometimes there are a few challenges.

Duane Thurman: I think one of the big issues on the table is this concept of updated reviews. And I think that it caught some participants by surprise is to, "Well, now we're done with this list, what do we have left to do?" And I think to have a truly evidence-based Preferred Drug List we need to keep looking at the new evidence that comes in and also take into account the new drugs that come onto the market. And I guess one thing, Jeff and Alison if you could talk about the difference between, you know, in the DERP 2 project they refer to drugs as being not selected for an update. But what we're talking about is the difference between a full update and something less than a full update when there isn't enough new evidence for a new drug in class to justify the expenses of a full update. And I think one of the things we wanted to bring before you today is the notion that, you know, how we'll treat, you know, because DERP gives us the outputs and then this committee has the discretion as to say, "Well, in certain circumstances the DERP group may not want to do a full blown update, but this group may decide that we need a full update." And so I guess if we could get a little information on what those scans look like for the drug classes that we're not going to do a full update on and then take a look at what those look like. And then the issue becomes once we step away from the DERP project we're acting on our own and we're no longer able to share the costs of these updates. And I think one of the things that came at the end of the DERP 1 project was our legislature directed us to do additional drug class reviews. They originally wanted us to do 25 more, and when we started to look at the cost of doing that alone, without the group of other participants, we really got to about two more drug classes before it didn't become cost effective anymore. And so, Jeff or Alison, maybe you could describe what it looks like when we're not going to do a full update through DERP? What product will come to this committee?

Jeff Graham: Well, I think there's two of those scans included in this packet today. And so you can get a good idea of what they look like and the reviewers do give you a little bit of conclusion of each report…of every article that's scanned. And usually what makes the decision for us that we do know there's a new product in that class or there's a new preparation in that class, and that's how the decision is made. And sometimes there could be some information. So far there hasn't been as much in the review as…our

knowledge that there's going to be a new drug in this class or there is one that's come out, or there's a new indication. But I think that…my impression has been they're fairly comprehensive. I mean, they can't do a complete update, but they do at least look at all of the RCTs that are out in that drug class or have been included in the literature since the last updates.

And I do want to…I think that we have as much input as anybody in this committee or our state that if we're aware that something's happening in a drug class that we know that's going to be reviewed or if you'll see the decisions that will keep you updated as to which ones have been decided to be included in updates and those that are not. That we should be aware of that. Because at the present time every year we'll have a report like this on every class that we've reviewed.

And, I wanted to mention I did send out an email to you all about what drug classes are indicate…or other diseases that you thought might be good for a new report. And I did get back one comment from the P&T members, which was very helpful that I passed on to Alison and them some of the staff had some comments too.

Vyn Reese: This is Dr. Reese. I want to thank Dr. Little for this service. It has been very helpful and is making major decisions about which drugs to include on the Preferred Drug List. I think it is an excellent service and you've done it in the past and I appreciate all the help you've given us. I think one of the problems, I think, is exactly as you've said: Reviewing what the legislature wants to review instead of what may be actually helpful, like the Macrolides, it was not a good review. And I think that was not a cost effective review. Or I think the legislature maybe needed to be presented with the evidence that whether these drug classes they want us to review are really going to be helpful for the state to do? I mean if the review costs more than the savings, it doesn't seem…it's not going to be helpful for the state.

Duane Thurman: Well, I think that this…one of the reasons we wanted to do this here was to set forth this new process because people want to know how we're going to update things. And I think one of the things we need to talk about in the future is, you know, probably at a future meeting is some feedback from the committee as to issues where you think certain drug classes may or may not be appropriate for inclusion on the Preferred Drug List? You know, unfortunately we're tied to a budget in terms of not being able to do everything. I think that what we're trying to do is accommodate the situation where we will do full updates when there are new drugs that come onto the market. What we're proposing is that the scams that you're seeing, we're calling them scams, those would comprise the update in the other classes, unless you as a committee decide that you think we need a full-blown update. And then that becomes my budget problem in trying to fund that update. But that's not your problem if you believe we need more evidence, then we will do that. If that then causes a problem where the legislature won't fund that, then we have the issue of saying, "Do you want to live by the evidence or do you want to take this off the Preferred Drug List?" And so I think that, you know, first we want to work this second phase of DERP, and then I think we've got to look at some issues we've been in existence long enough where I think it's appropriate for us to submit some information to the legislature about what the clinical expertise on our committee thinks about the kinds of decisions that you're making.

Dan Lessler: What occurs to me in terms of looking at the criteria that have been laid out to decide whether or not to do a full update and at least the two that I'm thinking about is new indication or new drug is, you know, I wonder whether…I mean whether you necessarily need to do a full update under those circumstances? And having something like that automatically trigger a full update might not be the best use of resources. And

I think a lot of…so, you know, because, you know, for example, a new drug can come on the market. It can have an indication which other drugs are out and available for that indication. The new medication likely will never have been compared head-to-head to existing medicine. And so to go back and sort of reconstruct essentially the same information except for what is going to end up being one relatively small difference, it seems like you're going to be putting a lot of resources towards something that doesn't have much yield in.

And yet there are other times I think of classes that we've reviewed here where over time there might be more important information particularly where there are head-to-head trials and to the extent that maybe even the DERP process drives industry to begin doing those trials. You know, that's where we would want to certainly do a full update. But have the time and…well for DERP to have the resources to be able to do it comprehensively and for us to be able to even take a little bit more time to spend with that update. So, I guess, you know, in terms of using resources, I guess, the message is it would seem that, you know, maybe having some further refinement of the criteria and just being careful as saying a new indication or a new drug is automatically going to generate a full update doesn't, you know, necessarily seem to be the best use of resources.

Jeff Graham: Dan, this is Jeff Graham. I think I would agree, but I think what happens with the participating organization…and I'll have to say with industry people here in the room, we get a lot of pressure from industry folks to make sure that we're transparent, that we're looking at the evidence and so forth. So, if we don't do that, we tend to get criticized and particularly we get criticized sometimes from legislatures and so forth. You're not keeping up with your process as you say you're going to do it. So I see that on both sides. I agree with your comments, but I also see that there are also other forces that cause us to do certain things. But I know this happens not only in our state but it happens in other states too. And that's why I think we're very careful to make certain that, "Well, yes, there is a new drug, no, it really doesn't make any difference." But, we have not really found the evidence to say, "No, it doesn't make any difference."

Patti Varley: This is Patty Varley. And I guess another committee fantasy I have has to do with the fact that if resources could be put into dissemination of the information because I think quite often what we have felt as a committee is that there is a lot of good data that this is generating, a lot of good information, a lot of good information, a lot of good education about those issues that are being alluded to, which is sometimes the more expensive newer one is not necessarily evidence-based better. And I guess my wish is that at some point along the way we find a way where all of this wonderful information gets disseminated to the actual prescribers, not by a limitation I guess on the PDL as what they see it as. And I know they have access if they go to the…but I…we also know that doesn't always happen. So that's just sort of a thought, as far as a future goal. This is great information and it has people thinking in a different way. And if there was a way to communicate that more effectively, I think that would be a great mission.

Dan Lessler: I would just second what Patti says. I think as well, not just to prescribing clinicians, but the consumers as well. I think that the, you know, the summary, the brief summaries, Alison, that now are put together that are sent to us are really excellent. And that the prescribing community would really benefit from having access to those. And they're probably a bit too technical right now for a layperson, but they probably could easily be adapted for a more general audience as well.

Jeff Graham: Dan, I want to comment about that. Actually, they're…there's something happening right now through the evidence-based or the Center for Evidence-Based Policy that is…there were grants given out to…how many entities about education?

Woman: Oh, the consumer prescriber?

Jeff Graham: Yeah. Anyway, actually, some folks at the University of Washington received one of those grants to educate providers regarding this evidence-based materials. I don't know where that's going yet, but there is something happening in this state. And there also are…then there were grants given out to educate consumers also using these materials that we receive giving more education. So I think that's something that from hearing you we need to learn how to take advantage of that.

Dan Lessler: Angelo?

Angelo Ballasiotes: You know, we are going to much to evidence-based information now and it's really kind of hard to keep up with the information in the different drugs and everything else comes out. I was wondering if there was a consideration of putting it on the web site that clinicians can…if they are having concerns about the effectiveness of the drug or anything like that or a synopsis of kind of what we're doing here and be able to click on that and get a fast read of what's going on?

Duane Thurman: Yeah, I think that, you know, really this is where we're moving into, I think, a different role in a sense for the P&T Committee. I think that is something we want to do. There are a couple pieces of very ambitious legislation being sponsored by the governor and others at the foundation that is focusing on evidence-based medicine. I think we need to educate both the legislature and, you know, evidence-based is not the "be all/end all". I think that a lot of people say, "Well, it's evidence-based. That's great." But I think, you know, we also need to point out the limitations of the process, you know, sort of the inherent messiness of it, you know, some of the lack of evidence, but I think the next step is to begin to educate and I don't know what's going to come out of the legislature. I think there will be lots of efforts like the Puget Sound Health Alliance and others where it will give us an opportunity to both focus on our web site to produce that sort of information, but to do it in concert with others because no one else is doing this. We're sort of out in front of everybody and we've been sort of feeling our way along. I think that in terms of the updated reviews, you know, one of the things that we have to keep in mind is that it's important that we honor the legislation that not even, you know, part of the updated reviews is this idea that even if it's not a preferred drug we have to dispense as written provision so it's very important for manufacturers to be able to get their drug onto the market and take advantage of that where practitioners want to use that drug and so our update process needs to take that into account to at least let those drugs be reviewed. Right now…and I'm going to ask Jeff to talk about this but, you know, we've had this sort of conversation over the last few years about, "How do you treat drugs that have not been through the process?" And we've taken a pretty hard line, which may or may always be in the best interests of evidence-based medicine, but if the drug is not considered through the Oregon process or if it's not considered by this committee it's not part of this program. It's treated as the individual agencies would treat any drug before this program began. And so I'd ask Jeff to sort of…I think you've got a handout here to explain what it is the agencies do in those instances just to sort of make it clear how important it is that, you know, why that dispense is written…language is in the statute.

Jeff Graham: Are you ready for that now?

Duane Thurman: Go ahead, Jeff.

Dan Lessler: Yeah, Jeff Thompson had a comment.

Jeff Thompson: We will continue to…I think Siri has done an excellent job of pushing the information out both with the academic detailing. We detail 120 providers that prescribe the most in a particular drug class every month. We send out notices to the clients for the…1,000 clients. So we will continue to, you know, do that education communication and then continue to post things on the web site. I think, you know, the HCA has done an excellent job with www.rx.wa.gov. The issue if we're evidence-based is that physicians don't use communication to change practice behavior, which is sort of a human condition. I mean none of us until something happens changes our behavior. So I would ask you to continue to work with us on the DUR section to where it is appropriate to do prior authorization or expedited prior authorization or to push out a guideline where there is some consequence or limitation. Quite frankly that is the way that we're going to really change things and it is supported by the good work that OSHU does, but just be the naysayer as the evidence says is that unless you put a process in the middle of communication where you stop and take a big deep breath nothing happens. So that's…I just want to compliment you. That's been the excellent work with the ADHD work. We'll be coming to you with some things on some other mental health drugs. It's been very effective in narcotics; it's been very effective in neurontin and neuropathic pain. So, you know, it has been very effective in the DUR portion and perhaps through the next rendition is both taking the evidence and then finding out how that rubber meets the road.

Dan Lessler: Thanks. Jeff Graham?

Jeff Graham: Thanks. Okay. I think we have…are these on the PowerPoint? These two policies from Medicaid and L&I? But they are also here on paper. Actually, I think it would be better if I let the staff from those agencies explain them because they are the ones that will be asked the questions.

Man: Are there copies available?

Jeff Graham: Where were they? I think there are copies, yes. There will probably be copies afterwards too, Bill. So Siri would you go ahead and go through the Medicaid HRSA policy? It is kind of small there.

Siri Childs: Okay. Thank you.

Dan Lessler: This is not in our packets.

Jeff Graham: It was handed out.

Dan Lessler: Oh, it was handed out. Thanks.

Duane Thurman: And we will post all of this presentation on our web site after the meeting.

Siri Childs: This is Siri Childs, Washington Medicaid and the HRSA policy and I'll read it verbatim is that drugs that are in drug classes on the Washington PDL that have not been studied by the evidence-based practice center or centers and have not been reviewed by the Pharmacy and Therapeutics Committee will be treated as non-preferred drugs not subject to dispense as written by the therapeutic interchange program. And then to go a little further to delineate the criteria that we look at

generally for a non-preferred drug…a non preferred drug, which the department determines as covered is considered for authorization after the client has tried and failed or is intolerant to at least one preferred drug and met department established criteria for the non preferred drug. Now that refers to our EPA criteria that we have across the board on some of the drug classes. I also want to say even though it's not printed here that because of senate bill 6088 we do have the refill protection in the atypical drug class and the antidepressant drug class that we currently have on the PDL and we honor continuation of therapy if they are started on samples in the physician's office. That is honored as continuation of therapy.

Dan Lessler: Siri, do you get any providers sort of commenting that, you know, that they write for something that is dispense as written and then it gets stopped because it hasn't been considered by, you know, by the formal evidence-based process?

Siri Childs: I've got to say that we get very few. So it does happen and we do explain our policy, but it doesn't come to my attention unless Patti Varley calls me. No, it doesn't really.

Patti Varley: It does happen occasionally. I would say it's not the majority of the time, but I do call Siri when it happens and it is a bit frustrating when I have signed the AW and they won't fill it. It's rare, but it does occur.

Jeff Thompson: This is Jeff Thompson. I will have to say that I think what's probably happening right now is you're seeing a collision between several of the other health plans and their formulary as well as our preferred drug list especially when you get in the mental health drugs, which we have a carve out program and that's where at least I see the confusion at the pharmacy level…

Jeff Thompson: …and some preferred drug lists we are actually where we would be more conservative. We are actually more liberal than the health plan and that is actually in fact confusing the pharmacists, the providers and the health plan.

Patti Varley: This is Patti Varley and Jeff I would agree totally that that's been the case is when that confusion has been the issue.

Angelo Ballasiotes: There's a case of frustration that I have run into a couple of times where…on DSHS our patients have been relatively stable on the medications and then they switch over to a different program or a different company with…I don't understand exactly how it works, but they have their formulary and we almost have to start inventing the wheel again and it's very disruptive to these people.

Jeff Thompson: This is Jeff Thompson again and that is a problem. I mean when you walk between different insurance plans there are different formularies and now Medicare has their own formulary with…what is it, 23? 23 formularies in addition to, you know, the typical health plan. So that is the world we live in and that is when I site the serenity prayer quite frequently.

Dan Lessler: I wonder if we want to comment on or look at the L&I policy then as well.

Jaymie Mai: This is Jaymie Mai from Labor and Industries. I'm not going to read it. It's there written and you should have the written policy in front of you, but basically we're very similar to Medicaid in terms of how we treat drugs that have not been reviewed by Oregon Health Science, evidence-based practice centers and you folks, the Washington State P&T Committee. The only difference I think in here is the criteria that we create for coverage of the non-preferred drugs. We actually will look at the indications

whether that indications been part of the industrial injuries and then we move on from there. But really that's our primary focus and the difference with the Medicaid policy.

Dan Lessler: Thanks. So…

Duane Thurman: Why don't we go ahead and cover the Uniform Medical Plan.

Dan Lessler: Yeah, okay.

Donna Sullivan: This is Donna Sullivan. I didn't put it in writing, but essentially what Uniform Medical Plan does if the drug is not on the Washington Preferred Drug List or considered within that class we use the formulary status of our pharmacy benefit manager to determine where it will be placed. As long as it's a covered drug then it will be either Tier 1, Tier 2 or Tier 3, but it depends on the pharmacy benefit manager's formulary.

Dan Lessler: Thanks. Any questions or comments relevant to the specific policies? Jeff, do we want to take a minute and just talk about the updates and the brief scans? My understand then is just to review that process is if the DERP decides based on the scan to go ahead with a full review then that will be undertaken. If not, then the committee, our committee here will review that scan and provide comment back to you all as to whether or not we agree that a full review is not needed or if we think otherwise and would suggest that a full review be undertaken. Obviously, at that point it becomes a point of available resources and so forth. But I wanted to touch base and confirm that that's the proposed process and then as well assuming that that's the case then I'm assuming we would formerly look at those or consider those scans where the decision has been not to undertake a full review and discuss them here as a committee. Is that correct?

Jeff Graham: That's correct.

Duane Thurman: That's what we're proposing, but I guess the point is you act independently as our clinical P&T committee. If you believe we need more evidence you do that without regard to whether we can afford it or not.

Dan Lessler: So I just want to make sure that the committee members here sort of understand that. I don't know if anybody has any other comment about that process? Okay. Are there any other aspects to this that we should be discussing here at this point?

Duane Thurman: Well, we talked about perhaps some of the stakeholders would like to ask us questions about this process and we're open to responding to those.

Patti Varley: This is Patti Varley. Before we do that I just…I think the other thing, again, in my fantasy mind is the issue that quite often the focus externally is looking at us and looking at this being a system to provide cost savings. I think there is a need for us to make sure that people are also very clear that as we review the evidence it's really for public safety and that kind of like you said that if we think a drug class needs to be reviewed regardless of cost that's what we need to do. And I guess I just feel like that sometimes needs to be reiterated and restated because we are in a world where everybody is looking at costs and money being the driver and I have to say that part of my commitment and what I tell people outside of here is that we're really looking at the safety of these meds, not just the cost savings and that we really are looking at the safety first. And I guess I just would say in the midst of all we are talking about that

that somehow gets disseminated as well on a repeated basis because I'm not sure that that message is always so clear.

Duane Thurman: Well, I can say that we haven't been called before the legislature yet to testify, but inevitably they want to know what the cost savings are and, you know, we have enough data to have some sort of a feel for what's going on and we're trying to put together our most recent estimates of that. But I think what the story shows is it's a lot more complicated than people expect. I get pushed back because a lot of times there's so much pressure on the agencies to save money that, you know, they forget about the fact that, you know, sometimes the evidence will say a more expensive drug is appropriate. Sometimes just because of the nature of…the fact the therapeutic interchange doesn't work in every case or isn't appropriate also changes the discussion in terms of what the lowest cost drug is. And so I think that the story that the legislature will…and I've been repeating this, you know, we're playing this program out as they've written it and I don't think that…I think there are some surprises. I think sometimes that the agencies are like, "Wow, we thought we were going to save this and now we can't say that and we're afraid to go out and do that." And I'm the guy who says, "No, we're going to tell them exactly what's happening," because this is…that's the, you know, you get the good and the bad. If you want an evidence-based system it isn't always about the lowest cost drug and I think that will become more apparent. I think there are people that would say, you know, "If we got rid of these guys we could save a lot more money." But, you know, they have stayed with it this long and I think we owe it to them to show them the full story and say, "If you're truly committed to this," you know, because ultimately what we don't have and what we need is…how is this affecting people's health? And that's the one thing we can't measure yet. So everyone just looks at the money.

Jeff Graham: This is Jeff Graham and Patti I want to thank you for bringing that up. I wanted to tell you that the comments you make here about safety and quality of life we take to our participating organization meeting and we particularly brought up the issue around Strattera and the safety of it because that drug class is being reviewed again and so that has been included. It was for all drugs, but I mean we certainly stressed that and so your comments here we do take very seriously when we go to our meetings with the other organizations.

Patti Varley: Thank you.

Dan Lessler: Thanks. So we can open it up for stakeholder input. Did people sign up or is there…there is no…folks, please feel free. Why don't we just…we've got some time, but maybe initially we can limit comments to three minutes as we normally do and see how time permits. If you could identify yourself that would be great. Thanks.

Bert Jones: Sure. My name is Bert Jones with GlaxoSmithKline. I'm the Director of State Government Affairs. I just have a couple of comments and then a suggestion. First comment is part of the pressures on the manufacturers is that it takes us anywhere from 9 to 12 years to get a drug to market and we have a 20-year patent life. So needless to say when the FDA approves our product, you know, we want to get it out into the marketplace as quickly as possible to get return on investment as it relates to all the money that we've spent on research and development. So that's part of the pressure on us. So getting it through the processes with health plans and Medicaid formularies becomes very important to us because we want to get reviewed as quickly as possible so a decision can be made so we can start getting our product marketed. That's my first comment.

The second comment is as it relates to methodology OHSU DERP has the process that's laid out with the basic three questions and of course I do realize that there's some more sophistication as it relates, for instance, like the diabetes questions, which I think are very, very good. But there is nothing in the methodology as it relates to pharmacoeconomic data and having a process by which that information can be, you know, made available to the P&T Committee. So I would like to ask that you think about that because there's some very valuable information that could influence a decision.

The other suggestion that I have and this echoes your comments, Dr. Lessler, about flexibility as it relates to your process. I don't necessarily think that you may need to do a review on a category because something could be done with the manufacturer as it relates to contract. I don't want to make any more comment just because of rules that I have to be under with the other companies in the room, but for instance I have a product that came out and was approved by the FDA in December and I know that OHSU knows about that and they are going to be doing the full review, but by the time that review is completed and a report published in November and just by your scheduling if you do hold a P&T Committee in December the soonest that my drug will become available on the market would be April of '08. So in essence I've sat on the sidelines for 14 months or 15 months. So anything that you can do to your methodologies and processes to speed that up would be very much appreciated by GlaxoSmithKline.

Dan Lessler: Thanks. Any question there or comment? I appreciate your input. Other…

Patti Varley: I actually am going to make…this is Patti Varley. I'm going to make a comment first. That is at least to date the dilemma for us in looking at new products is the lack of methodology in drug development of head-to-head studies done by companies against meds that have been previous FDA approved. So I would say back to you as far as methodology goes if we had better evidence that would help us. So the way that drug manufacturers data is provided to us isn't always giving us all the evidence we would like. So that is back to you. I think we could both do it better.

Dan Lessler: Yeah. If you could just identify yourself, please.

Christopher Connor: I work for Pfizer. I'm a Clinical Pharmacist. Just one comment and it's how encouraged I am that there's an emphasis now to look more at effectiveness studies when evaluating these classes and the one thing I think we have to keep in mind is the debate between efficacy and effectiveness. I mean you all here are entrusted in making decisions about Medicaid beneficiaries. The characteristics of that population may be very different from the patients that enter into a lot of these randomized controlled trials and anyone who has been involved in the randomized controlled trial process can understand that the inclusion and exclusion criteria are very specific and may exclude many of the patients that you treat, you know, on a day in and day out basis. So I'm encouraged that you are now considering this evidence and weighing it a little bit more because up to this point the methods have been biased towards these very specific randomized controlled trials. So I mean my comment is just to remember that, you know, you are making decisions about populations of patients that are very special. They are Medicaid patients in the state of Washington and I look forward to seeing these reports that look at these more effectiveness type studies, retrospective studies that look at these kinds of patients, Medicaid patients in particular. Thank you.

Dan Lessler: Thanks. Yeah?

Sabrina Arey: Hi. Sabrina Arey with Bristol Meyer Squibb. I first of all just wanted to just express we've been very appreciative of the open nature of this committee and with the Oregon center for the ability to provide stakeholder input and manufacturer input into all of their reviews. I think what I'm confused about is if the scans are going to be used by the committee how will we know which categories are going to come up for the agenda and will there be any ability of manufacturer input into the updates of the scan? I guess I'm a little confused of how that will continue to roll out or work by the committee.

Dan Lessler: Jeff, do you want to…

Jeff Graham: Well, our intention is that we would probably…the agenda for our meeting and that we would know that we're going to review a scan and everything that we read you get to read too so that you would know that we have stakeholder comment at that time. So that would probably be one way to do it. I believe that's our intention and that's what we've talked about.

Vyn Reese: This is Dr. Reese. I've got a couple of comments. I too wish we could look at pharmacoeconomic data, but we really…that's been taken out of our per view and it's the various agencies that do the negotiating for the drugs. So we really can't comment on that. So we've been unable to do that and that's outside our area. The other thing is about the delay in new drug reviews. Sometimes it's a good thing. A lot of times it takes a year before a drug is released in the mass population to see if there really is a serious side effect that has not been recognized in smaller trials. And so it may be safer for the state's patients. So not as good for the manufacturer to have that happen, to be a little slow to review and see what happens with all the other patients that get it before we add it to our formulary. It's a two-edge sword and I can see that the…it's a very cumbersome process we have with so many drugs to review and every sever months we review and then we look at…we review other prior reviews. So it's slow, cumbersome. It may be a little safer, but not as quick and decisive as you'd like. So those are my comments. Thank you.

Dan Lessler: Other comments from P&T? Is there other stakeholder comment in the audience? Yeah?

Bill Struyk: Good morning. Bill Struyk with J&J and I just have a couple comments. Patti, the one…I agree head-to-head trials would be useful, but if the manufacturer generates them there seems to be Sinicism about the results. So damned if you do and damned if you don't.

Patti Varley: Right.

Bill Struyk: Dr. Lessler, I have a question for you. You said that you were unsure whether or not a new indication or new product would generate big criteria sufficient to generate a new review. Given the constraints of 6088 in DAW how would you suggest that be handled if a new review wasn't completed? Particularly in view of the fact that, you know, the criteria that the agencies stated?

Dan Lessler: You know, I'm not exactly sure what the process would be but I would envision is some kind of expedited review that sort of indicates, you know, this is the only change here and hence, you know, there isn't a need to redo the, you know, the entire review so that…obviously, you know, it would have to be some mechanism of indicating that the medication had been reviewed and allowing for an update, but I'm just concerned…

Bill Struyk: Whether it's a full update?

Dan Lessler: Right. It just seems like there are circumstances where a full update wouldn't be indicated. That's a good question. You know, I also just want to comment on your comment about head-to-head trials. My own sense is the DERP has laid out very clear criteria as to what constitutes a high quality head-to-head trial. What I have seen in my reading of, you know, of the DERP reports where there are head-to-head trials that are…and the outcomes are discounted because of the methodology. I think there is good reason to doubt the outcomes because of the methods. So what I would say is I suspect and maybe Alison can comment that if manufacturers began, you know, adhering to the criteria that are required to conduct a methodologically rigorous comparison that it wouldn't matter whether it was coming from, you know, industry or not. Alison, maybe you could comment on that.

Alison Little: Absolutely. I agree 100%. There's nothing specific about industry-supported trials that makes them poor. It's how they are conducted.

Vyn Reese: This is Dr. Reese and we've several industry trials where the doses of the drugs weren't comparable and that was the reason they were discounted is because one dose was twice as potent as the other for two different drugs and the manufacturer's drug had twice as potent a dose and so it was more effective. So you have to discount the trial because the doses were wrong. So I mean it's like…and that's happened several times. I understand why manufacturers are reticent to have trials because you could actually fund the trial and find that the other drug was better and that's not a good thing. So it's a…I can see how that side works, too.

Patti Varley: This is Patti Varley and there was this situation where a lot of data was there, but not published because it went against a product that somebody was trying to market and we understand that, too but that does bring up that cynicism of that methodology question.

Jeff Graham: Dan, I'd like to make a comment. This is Jeff Graham. I did want to comment and thank the pharmaceutical manufacturers for looking at our web site, making comments on key questions, making comments on the draft reports. Since I get to sit in on those meetings of the participating organizations you make many very good comments and point out where we are deficient in sometimes our key questions or we may have interpreted it incorrectly and particularly on the draft reports where very good comments are made and those are included in the final reports because you will never be able to find them, but they are there and we certainly appreciate that.

It's been a big difference in the last two to three years on how you respond to those things and I'll always say to you when somebody calls me, "Make certain you have somebody in your organization who's looking at that web site," because those things come up weekly and you could miss them because there is a time limit on the time for comments. I think many of you are getting very good at it. So we are very appreciative of that. I am. I mean I think the participating organizations are too because it does enrich our whole review.

Woman: Can I say something?

Dan Lessler: Yes, please.

Woman: I wanted to go back to the comment made about the delay in sometimes getting to the drugs to review and one thing I'd like to say that looking at it from both sides and having sat on other P&T committees is that some of the information that you get out in your studies there may be a small indication of a complication and by waiting and the delay like you said it might be safer for our patients, but it's also better for the manufacturer because some of these things can come back to haunt you and if you look at the big…it's a risk management thing for you and also you watch the big judgments against the company and then your stock falls. So I think that while we're looking out for the safety for the patient, it's also good risk management for you because you may have some of those small indications and it turns out to be a big indication and there's trouble along the way. So sometimes that little wait is best for everybody.

Dan Lessler: Any other stakeholder comment? Okay. Very good discussion. Jeff, is there anything or Duane anything else in terms of…? Okay well, Alison, I just want to add my grateful thanks to the work that the DERP does. It really is outstanding. I know I learn an incredible amount from reading the reports, I think, and the committee when we have our lunch together each noon hour during these meetings the only thing we lament is that we don't get continuing education because we certainly learn a lot. So we really appreciate your work. Thank you very much. I would also thank everybody else from the agencies and Jeff for all your good work. It really, I think, is a worthwhile effort that is making a difference. So thanks a lot.

With that I think actually we'll adjourn a bit early and reconvene at 1:00 and actually as I mentioned Dr. Reese will be chairing the afternoon session. So thank you.

Vyn Reese: Dan Dowler, Chief of Program Support for the Division of Medical Benefits and Care Management will present now on DUR for Washington. Is that right?

Dan Dowler: Thank you Mr. Chair and the members of the committee. I'd like to introduce my associates. To my right is Ruth Leonard. She's with our division of alcohol and substance abuse—part of this project. And Scott Best who is in our patients review and restriction program, which will also feature as we go forward in this presentation…this is a very informal session. We have about an hour and a half or so dedicated to this as I understand. Is that correct? Okay.

So what we'll do is we'll go through a PowerPoint to give you an overview of the project scope and the strategies involved there and then in this process we're also going to demonstrate various tools related to this toolkit that we're ushering into these four counties. By way of introduction we have launched a…kind of a multi-disciplined approach across our entire department using community physicians where appropriate and developing some things. I know your committee was instrumental on helping on the opioid dosing guidelines that we've been talking about recently as well. And in that discipline we've involved our division of alcohol and substance abuse, which Ruth is representing today. Our mental health division, our aging arm of our big department, and our committee of about 20 people have implemented what preceded this effort, which was our narcotic review project where we targeted individuals who were in excess of ten narcotic prescriptions in a month and began to do some interventions and those interventions, part of those interventions were using a comprehensive profile, a drug profile, a narcotic profile, which when we gave to the physician community and gave them a much more enhanced perspective with that new information they interned and influenced the way they were doing the prescribing practices with those targeted individuals. This is not too dissimilar in that we focus on a different population. We'll talk about that.

And then we're using a toolkit, which we've enriched a series of resources and materials for the physician community to use and we built a web page around that. So we'll show you the horsepower of that interactivity as well.

So with that this is the title cover page to our presentation today and Ruth is going to take the next couple slides and I'll go over there and advance them for her and then it will bounce back to me.

Ruth Leonard: Okay. So in the last legislative session DASA was awarded additional funding, $33 million, to expand access to chemical dependency treatment services and deeper penetration into the needy population. Our priority population with this added funding is the Medicaid, SSI related, age, blind and disabled folks and the GA-U (General Assistance-Unemployable) adults with chemical dependency treatment problems. And our goal, obviously, is health related savings. Go ahead to the next slide.

This is a flow chart just to provide basic information on how to access chemical dependency treatment services. If a person who comes in contact with a client, it could be a physician, a pharmacy, a nurse, the patient review and restriction staff they would hear or see that there is an issue or concern. If they felt it was urgent they could refer directly to a county detoxification facility or they could refer to a local hospital to get immediate access. If that wasn't immediately available to them they could also call the 24-hour help line and the number is found in the middle of the screen and that person at the help line would be able to direct the individual to treatment services in their local area. If they didn't feel the need was urgent, but still wanted to make sure the person got referred they could refer them directly to a chemical dependency outpatient treatment program. They could refer them to a residential program who would be able to do an assessment and make appropriate treatment recommendations. They could refer them to an ADATSA assessment entity and they also would do an assessment and make an appropriate refer or they could then also call the 24-hour help line. Again, the 24-hour help line information is found in the middle of the screen and the goal, obviously, is to hook that person up with the appropriate services treatment…

Ruth Leonard: …and then these are some strategies that we have used. We found that this population is difficult to reach and part of the reasons it's so difficult is that our system, the chemical dependency system, is set up as a patient comes to us type system and many of the folks that we're finding need these treatment services, the age, blind, disabled population they are used to having a system where the services come to them. With the aging system the case managers come out to the home, the nurses come out to the home. So it's difficult for them to access our services. So we've developed new programs including a group care enhancement model where we have folks out in the community who can go into the home. They are going into nursing homes, group homes, HUD housing facilities where we know there's a larger population of folks in this category that we're trying to capture to provide screening, assessment, education for the staff and for the patients or residence in those different communities. We also have the four county project, which you're hearing about today. We've added additional chemical dependency treatment providers. If there are local providers that weren't currently contracted with the county or contracted with DASA directly. We went to those providers to ascertain their interest in contracting. If they were so interested either the county or the state would contract with them directly to provide services and then we continued to look at increasing the services for GAU clients.

Man: Feel free to ask questions as we go through this. Yes, sir.

Angelo Ballasiotes: I'm from Yakima County and I wonder if you folks have the treatment centers to meet the demands? And then your point is very well taken with regards to access. You have a very difficult time in getting people in the treatment, but who is going to pay for it? What's the fund now?

Ruth Leonard: As far as the access issue we were talking about that earlier today. Part of that access piece will depend on the person's ability to navigate the system, which to me is unfortunate. So sometimes you have to know the right person or know what to say, know who to keep bothering to get your treatment services.

Angelo Ballasiotes: You're going to have problems with that. That's going to be a real stumbling block.

Ruth Leonard: I agree. And that's one of the reasons that we put (1) counselors out in the community and with this project we've assigned staff to be responsible. So mine for Clark County if somebody has tried to access services and they are having difficulty we want them to go ahead and give us a call. So if you're in Clark County and you're having difficulty or you don't know who to call, call Eric Larson who is your regional representative and he should do that extra legwork for you.

Angelo Ballasiotes: Example. By the way, we have the only female inpatient program in the state. And we have [inaudible] of kids due to chronic pot, meth and alcohol use. She would really benefit from being in this inpatient program. There's no question in my mind. She [inaudible] treated. She lost her kids. The question is which, "Should she really get them back now?" because of her past behavior. I tried to get her in, she didn't have the right coupon and it's really, really terrible. And a result she's just going to get the one leg at school. She's just going to get the [inaudible] treatment. She needs more to be effective…for her to…for her treatment to be effective. So what I'm hearing you say that you folks could maybe get her into this program with different funding.

Ruth Leonard: We could work on that. I can't ever guarantee. We would have to look at the situation, look at what her particular case is, see what her funding is, but I would say call and ask the questions because for me and I know for Eric we'll go the extra mile to work with the patient and with the person to do everything we can to access services.

Angelo Ballasiotes: We capture, but we don't have much time.

Ruth Leonard: Right. And I agree with you on that. Again, we have people out in the communities for that exact reason. If you're out in the community and you need to get an assessment, but you have the transportation barrier and you have medical issues and there are three or four things making it difficult for you to get in and they give you a certain appointment and you can't get there at that time. How many times, you know, are they going to go back and make an appointment?

Angelo Ballasiotes: You can get the assessment and we can get the people there to the assessment.

Ruth Leonard: It's the treatment after. Yeah.

Angelo Ballasiotes: It's a real [inaudible], you know, trying to get them into the program. Depending on what coupon they have…

Ruth Leonard: It's true. Yeah. Call us. We will help you.

Angelo Ballasiotes: What makes it effective? You know.

Man: Any other questions in that regard? Okay. What I just gave out is…

Siri Childs: Dan, did we really get an answer? Is the answer that just to call and work through it?

Man: Yeah. When we launched the first two of the four counties the focus on this pilot project of what we call the alcohol and other drug (AOD) project was to launch it in four counties. We've launched it in Yakima County, Clark and then we'll be following in about 45 days with Pierce and Spokane. And in the Yakima launch we got some good press coverage, we got a moderate turnout considering the snow storm that we have to encounter over the pass when we got there, but Eric Larson who's in this toolkit hard copy I just handed out to you, he'll be on page two. The first page is a cover letter from Dr. Thompson who I know sits in this committee introducing the concept and I'll orient you to this toolkit in hardcopy form and then we'll show you the interactivity on it in the web page. But Eric was in attendance at that session and said he would welcome any calls from practitioners, from community members, anything that would involve problems, delays, because part of the goal was as we coordinated with our other partners within the department was to make sure that we had the ability to respond and that's part of that critique.

Man: That's very critical in our county.

Dan Lessler: So no other counties are being served at this time? Or the program is only in those four?

Man: Well, the…Ruth's division of Alcohol and Substance Abuse has a statewide presence. They are statewide in their service, but what we wanted to do is in launching this initiative to target individuals and to go deeper into the resource pool to make sure people got what they needed we kind of lined up the resources and made sure that they were ready and we were going to target it in these four counties to see if we get kind of a response, the kind of support, the kind of referrals for increased screening and treatment that we hoped to get. If it worked well and our evaluation showed it was worth that kind of coordinated effort then we plan on implementing it throughout the rest of the state in a coordinated fashion.

Dan Lessler: If you could get the resources and the beds that's the key thing because there is always this horrible shortage. It's hard to get people in. That's been a problem for years.

Man: Yeah, and Ruth could probably clarify. I'm still vague in my mind what distinguishes an inpatient treatment approach versus an outpatient treatment approach and how they triage that and tease it out as to what's more appropriate.

Man: [inaudible]

Siri Childs: I have another clarifying question. I'm under the impression that our pilot program starts with a list of targeted clients and then we are providing information to prescribers and so it wouldn't, Angelo, be a situation where you might have a client that's not in the targeted population. I mean you're always welcome to call, but the focus on this is that we've selected the patients and, you know, I think that will be made more clear as they show us what they are doing with those targeted clients that have been selected because of their high drug use and alcohol use.

Man: I'll elaborate on that because Siri's right. What we did is we basically looked at individuals that met a certain medical diagnosis series, if you will, within our MMIS (Medicate Management Information System), our bill paying system and then

identified those individuals and linked them to practitioners that had served them, prescribed to them, and then when you look at this toolkit, the hard copy version, it's worded to the provider that there will be attached this 12-month medical history. So there's really two major prongs to it. One is the toolkit itself, which we'll talk about, which is a good resource for anyone in the community and then the second prong of this is focusing on a particular population and linking that population to the provider community that served them and then getting that comprehensive medical profile in its three forms, which we'll talk about to that physician or that prescriber and then allowing them to see this comprehensive picture that they may not have seen prior to that…arrival of the profile.

What we learned in the narcotic project and I'll draw your attention to the top of page three. That slide is in reviewing the excessive narcotic population we saw that the excessiveness were often strongly correlated with ER use and this cycling process we saw was happening. They would come…the individual would come and go out of the ER rooms as they were seeking narcotic prescriptions and it seemed to be a correlation in our findings and we'll show you a couple of slides in that regard. The population also showed us that certain diagnosis, those associated with headaches, abdominal pain, lower back pain were being treated in some cases successfully with chronic narcotic use and many times that use was coming from the ER world. So we're trying to engage the emergency room physicians, the emergency room administrators and others in our presentations that we're trying to arrange now for our Pierce and Spokane efforts to engage them even more so, so we can get them to correlate the connection here on that population.

Our medical mental health and our divisional alcohol and substance abuse administration and the community joined together in this coordinated activity. So it's kind of breaking out of our silo approaches that we had used in the past and kind of creating a comprehensive multi-disciplined and multi-programmed team to roll us out into the community. And the medical history profiles I eluded to just a little bit ago were this comprehensive picture and we'll talk more in detail about what's in that profile, which would give the practitioner better opportunities for treatment and medical care that they otherwise might not have and then the toolkit in this interactive web site we developed so we could provide a new and improved resource enhancement kind of model for them.

The next slide is difficult to see up there, but on the bottom of three let me orient you to this slide. The X axis across horizontally you'll see an arrangement from no visits, a sample size, all the way up to 31 or more visits to the emergency room in fiscal year '02. On the Y-axis on the left side 0 to 100%. And the top gradient is kind of a light gray on the slide are those individuals with mental illness only. The middle gradient, the smaller one, thinner one is the alcohol or other drug disorders only. And the bottom, the darkest is the mental health and co-occurring disorders as I recall. I can't quite see that, Scott, up there, but I think it is. So when you add up the three you end up with about an 89%. The resolution is pretty poor on that, but you end up with about 89% when you add all those up. You can see that the gradient keeps increasing the higher the number of visits and the more common these co-occurring disorders or mental illness or AOD the higher your profile on the right hand side. So we're definitely seeing the more ER visits the more common these individuals present with these kinds of issues diagnostically speaking.

The next slide correlates for you the prescription patterns in that same population. We looked at the average number of pain prescriptions is highest among those most frequently visiting the ER and you'll end up on the far right hand side with 42 average

number of narcotic analgesic prescriptions in a calendar year for those at the highest level of 31 or more visits and then it goes to the left showing you this correlation with the ER activity and the prescription activity that's occurring as well. So what we did on the next slide is we took what we call the four-fold strategy that we used in our narcotic population. So on the top box we substituted the population that we're talking about here, the chemically dependent individuals, alcohol, diagnostic codes or other mental health issues related to those…or those three occurring, two or more occurring together. We identified that population with what we call a high risk opportunity population and then we're using an approach that we used in the narcotic world where we're doing an educational communication intervention, which is part of this effort as well as our meeting with provider communities, but we're sharing the medical history as part of an educational intervention or outreach with the physicians. We're showing them an ER profile, an emergency room profile in this comprehensive medical profile that will come to those that are targeted in this population. We're showing them a prescription profile and then what we call other. So it falls into three categories: emergency room use, drug use/prescription use and then other and we break it down and send that to those targeted providers.

And then we introduce them to use this toolkit, which we'll talk more about and the web page. On the right side of that is the prescriptions and utilization management. In the narcotic world we would actually suspend claims for prior authorization review and then engage the physician community to see once they looked at that profile what they wanted to do. We could do something similar, but have yet to do much in the prior authorization world with this group. This is more of an educational intervention. We also use in the lower left side patient review and restriction, which Scott will talk a little bit more about later on about the PRR program. And then on the far right hand side are partnerships with DASA and mental health is part of our case management intervention so that we can get these folks into screening and treatment. So that's sort of the four-fold strategy we're using in this project.

The new toolkit, again, focuses on trying to increase the amount of referrals and treatment for those individuals that would be eligible for drug and alcohol substance abuse screening and treatment and then coordinating with the provider community. We've already talked about the folks on the four counties and then statewide if successful. Still dealing with narcotic review and prior authorization as appropriate, PRR as appropriate and then coordinating with our mental health and our dual diagnosis programs, which are outlined further in our toolkit, which I'll talk a little bit more about later.

This next slide is just a snapshot of the actual toolkit that I just gave you. The cover letter introduces to the provider the possibility of partnering and getting information to help them. As you see from the cover letter from Dr. Thompson the third paragraph, "We are offering you a set of tools that will help you get the necessary care to your patients," and then identifies in this targeted mailing the profile that would be attached at the time that the practitioner receives the mailing. And we'll talk about what that profile looks like. And then it encourages the practitioner, the recipient of the letter to save that middle bold paragraph, the URL or the web address within their favorites so they can interact in this web page at any time they want to from there on out on any clients that they are trying to serve better.

We focus in on major bullets. Six, getting your patient assessed and potentially into alcohol and drug treatment, new and innovative treatments for chronic pain, lock in programs, which is our PRR program to curve abuse and misuse, dealing with case management resources for those folks who are [inaudible] and disabled, their unique

resources and networks established out there in the community, social community and medical community, and we link to that. Getting a 12-month prescription history in reducing narcotics. That's our previous project. We get them reoriented to that if that's helpful to them and then resources that are available for those that are dually diagnosed. The structure of the toolkit and the web page follows that six-bullet approach and it identifies the links, which you see static on the piece of paper, but we'll show you the demonstration of as we go through.

This next slide is an actual highlight of one of the pages of the profile and we left in the gray bar because there's a current unique restriction in Washington State law that requires an expressed release from your patient if that patient has a mental illness. We cannot reveal diagnosis codes on mental illness without express authority or release from the client nor their associated drugs that may be used typically to treat those illnesses. So this gray bar is to illustrate to you the things that we're dropping under the current state law that you would not be able to see if you were one of the targeted physicians getting this profile.

We have also simultaneously worked with the legislature and there is a bill sponsored and is going through both the House and the Senate and has received favorable hearings and has been recommended as do pass out of both of those chambers. So it's on its way to a conference committee and hopefully will get to the floor for a vote. And that RCW modification would allow for a limited revelation of this material from the get go and it would do so in a way that's clinically sound. It would get that information to the clinician…to the provider community and do so in a way that respects the confidentially issues by building them into the law so there's no express release. It would also enable the department to notify clients when such is done. If that passes out of the state that would change the way we are approaching this pilot. So we'll see how that goes through this session.

The next slide is an actual snapshot of the web page, which we can demonstrate to you a little more interactively and Scott will slide through it, but this is just a snapshot of that page and we'll jump into that at the end of our presentation. Scott will jump into the patient's requirements and restrictions part of our program and then we'll come back to the actual web page and just kind of bounce around in it so you get a sense of what it does. I'll switch places.

Scott Best: Patient review and restriction is a health and safety program to assist fee-for-service clients and most recently we've had some [inaudible] changes that allow us to use it for clients who are in managed care to help them to appropriately use medical services. We find that clients often times over-use or inappropriately use medical services and the patient review and restriction program, which is described in CFR 42 as a lock in program is actually a program that allows us to lock a client into one primary care provider, one pharmacy for their prescription fills, and one hospital for non-emergent care. We have found that by doing that that we help clients to reduce their over utilization. For clients who are in the PRR program they have a 33% decrease in emergency room use, a 37% decrease in physician visits, and 24% decrease in number of prescriptions. A lot of those prescriptions are of clients who are over utilizing narcotics and psychotropic medications and therefore it fits hand-in-hand with the program and the toolkit and the goals of the toolkit. We…everybody wants the clients who are having problems with over utilization of narcotics to be able to get into treatment. You mentioned that earlier and one of the things we do is we lock them into certain providers and then if they are over utilizing they have to get everything from those providers and it prevents them from going elsewhere to get medications. We find that a lot of them are doing polypharmacy and going to multiple doctors.

We get a lot of our patient review and restriction clients come through referrals and a some of the referrals come from the billing information that we look at and then other referrals come through telephone line and through fax and through email and we are able to then look at those clients and so as a part of this toolkit we are trying to encourage providers to refer clients to the patient review and restriction program and then they will be directed in another way towards getting the treatment that they need in the cases where they need treatment.

In the slide it gives you the patient review and restriction referral line and it also has the web site. If you go to the toolkit web site it also has links there that take you to the patient review and restriction program website, which assists clients to get that same answer from everywhere they go that they need to get the treatment that they need.

Man: You may remember from a previous meeting Scott was here talking with you about development of opioid dosing guidelines and because that is in a pilot phase now implemented for the physicians to use, to consult with, to evaluate in light of their patient's needs we built that into the toolkit as a resource. So when we demonstrate the web page you'll see that there is a live link on that set of guidelines at this stage of the game. When those are permanently posted in the AMDG web page, which I understand is underway…under development now not only will that be a final product, but built into that product will be a link to a opioid dosing calculator, which will help the practitioner evaluate the morphine equivalence in a practical sense doing the math and helping them calculate those dosages correctly. By either using their own information, by using the profiles that we've got or combinations of both or patient histories, intake, etc., they should be able to better evaluate the total morphine equivalence of the prescriptions that they are providing or that they know are being provided to their patient.

This is just a snapshot of that guideline and Scott's going to demonstrate briefly that calculator. We'll show it to you and then we'll jump into the web page demonstration before we wrap up.

Scott Best: This is the calculator [inaudible] Excel. [inaudible] developed the calculator by…it was developed by some people from Labor and Industries, some of the doctors [inaudible] Labor and Industries and what it allows you to do is it allows you to go in and put in the dosages…daily dosages that you have for different medications. I have a client that…I have a copy of some dosages that they had. This happens to be a patient review and restriction program client. He was on 75 micrograms per hour so if [inaudible] 75 micrograms and then it immediately lists what the morphine equivalent is for that and then it calculates the total down here. This particular client happened to be on hydrocodone at the same time from a different physician and he was…his daily dosage of hydrocodone was 22.5 mg. Then it asks the morphine equivalence for the [inaudible] morphine equivalence for the hydrocodone and it comes up with a daily dosage of 202.5 morphine equivalence for the client, which is well beyond the 120 morphine equivalent and should be an indicator that the client may be getting too much. When we were looking at [inaudible] for reviewing the restriction program often times they are going to multiple physicians and getting narcotics from all of them. This is a quick and easy way to be able to tell if they are getting too much from all of them put together.

Man: So it's an interesting kind of joint venture here with the physician community, the pain specialist community, which we are also consultants as I understand it in developing the guidelines. With its pilot launch to say if this information is available and it's

available on all of those seven where there be some sentinel affect as a result of having this available? It's relatively straightforward. It will be interesting to see over the course of time how well that enables the physicians to do things differently in regards to prescribing. It's kind of a high road approach in terms of the education and interventions that we're doing with the medical community.

Man: [inaudible]

Man: Yeah.

Angelo Ballasiotes: I have a couple of questions with regard to [inaudible] in Yakima County and [inaudible] the ER and hospitals [inaudible] to treatment and comment on that.

Ruth Leonard: What you're referring to is the Washington Brief Intervention Screening and Referral Project. It's in ten hospitals I believe across the state and it's not my project directly, but from what I'm hearing report is many people are getting referred into treatment. They are seeing great benefits just from the brief intervention. Even for those that don't go onto treatment because it's not really geared toward chemically dependent people, but people who are on that track. So somebody who may be abusing that brief intervention is being found to be very successful and then the referrals into treatment are quite helpful.

Man: [inaudible]

Ruth Leonard: Right.

Angelo Ballasiotes: Now I'm wondering…if we could get just to our [inaudible] people who come to our clinic [inaudible] a lot. I wonder if we could get a print out of all the people and we could get a jump on it…well, not a jump on it, but intervene.

Man: There was a gentleman during our Yakima presentation…Ed was there, but I'm trying to think of…they worked at one of the two hospitals in Yakima. It was a physician. She was from the ER area and she was speaking about…they had retained a pharmacist to, if you will, profile the group of high users, high flyers, frequent flyers in their ER room, and then by engaging that consultant pharmacist they were able to work in a more planned fashion when they re-engaged that same patient and then manage that approach in the ER room differently just by recognizing who these folks were and having a set of information that was readily available. She said it was quite successful, but she recognized that unless that was done likewise in other clinics or across town they might effectively influence the utilization pattern in that ER room, but they might end up going across town and surfacing elsewhere. So she admitted that a comprehensive community approach was needed there.

Man: [inaudible]

Man: And I've got her name on a…

Man: [inaudible]

Man: Well, case management is such an interesting term because in the aging world…we'll show you the web page here a little bit more. In the aging and adult services world there are case managers assigned to specific clients served from that division. So they have a case manager. Ruth and her team have similar kinds of labels on some of their folks that are managing the portion of business dealing with the alcohol and substance

abuse. I know that mental health has similar terms and so the whole definition of…Scott said polypharmacy. We've got poly case management going on. So we have to try to help one another work on who's on first on this particular case? What aspects are you tackling? How can I compliment the effort? I'll do this piece and coordinating that amongst case managers is a real challenge when we have so many people if you will similarly tasked to do that job. It becomes a very complex problem. Yes, sir?

Man: This may be more of a question for Siri, but it sort of begs the question has DSHS [inaudible] a much larger scale for medical patients? If anyone comes to our practice as a new patient we're going to say to him, "I need you to sign this piece of paper to release your old medical records so we know what kind of health care you've gotten in the past." We don't have that power necessarily when we see Medicaid patients. Wouldn't it be nice if…whether it was about substance abuse or [inaudible].

Siri Childs: I think this is exactly where this is going because this is DSHS. This is HRSA. We're all working together—the drug program, DASA, mental health, we're all part of the same organization now and we're working together to try to bring you as much information as we possibly can so that you can make a difference in these people's lives. And I can tell you right now that if any of you need to have specific information on a specific patient I have been known to provide you that information with a telephone to me. You have to ask Patti first.

Angelo Ballasiotes: You know, by in large these people do get better. I don't think [inaudible] understand that. When they start feeling better and they understand and then they relax and [inaudible] feels better. They stay clean and sober longer [inaudible].

Man: To illustrate the recognition of this on a statewide policy basis this morning I'm on a [inaudible] bill. I don't recall the bill number right off the top of my head, but it is a bill that Senator Hinkle is the prime sponsor on and it is creating a database that dispensers would contribute to on a routine basis and a very frequent basis. There's some debate on what that means, but it would give the Department of Health a repository of all the scheduled two through five drugs used as prescribed on a routine basis by the dispensers and that would be made available to practitioners, state agencies as needed, and the Department of Health would maintain and operate that on behalf of the effort. There's some questions about ongoing funding, there's questions about what's meant by real time in the bill and technical details that are being discussed at this point. It got a favorable hearing in the house and the Companion Bill and the Senate also received a favorable hearing. So there may be some more momentum in terms of a comprehensive kind of approach particularly when it comes to the schedule two through five drugs. So that's encouraging that that debate is occurring at the legislature, too.

I'm going to orient you a little bit to…you've got a hard copy of this, but if you'll kind of focus on the screen up here. This is an actual…what it looks like, our web page. If you go again to the first page of the packet I gave you and you see the letter from Dr. Thompson. Save that URL in your personal computer and it's in a public domain and it will take you to this page. This is embedded as part of our pharmacy addressing within our Internet and you'll see it introduce the scope, you'll see that leading in paragraph on the left side of that oval picture and that introduces the scope of the concept that we're talking about—helping patients with drug use disorders. And then as Scott scrolls down the page…let me orient you to it. There's four or five major headings. The chemical dependency treatment heading and there you will see names of people both in Yakima and in Clark that were part of our roll out in those counties

and Ruth is there on that list. And then as we move into Spokane and Pierce those names and contact numbers will be added. And there will be some links that Scott will demonstrate as we go through it. The second major category is the treatment for chronic pain group and there is a variety of resources and tools there, as well. We'll show you those. And then curbing abuse and misuse links us right back to what Scott was talking about—the guidelines and patient review and restriction and the narcotic project. And then the case management major heading that's dealing with our aging and disabled partnerships and the clients we serve that are aged or disabled. Unique needs rest with those people and those individuals are linked to the web pages maintained by aging and disability services. So we're getting all the fresh and latest refreshes on those just by linking to them. And then the last heading within that main page is our dual disorders links and we have both Yakima and Clark County listed and we'll expand those, again, to the Spokane and Pierce venture as we move out there as well.

So Scott will roll back up and kind of run us through the links on the pages that are embedded and you can get to them on the left side, too. There's a quick ready reference point on the left side that takes you through the entire thing or you can roll through and link to those embedded in the web page.

That first one is chemical dependency. That is a web page based to give information on treatment expansion, the thing that Ruth was just talking about. It gives you the latest information, page references, details, phone numbers, contact people and guides, things you can post in your office, etc., etc. So it's a very resource rich link that will constantly be refreshed with new information. So that's built right into the web page. Then there's a further link down below and Scott will click on that and that will come up. We've had very favorable reviews so far in the people we've launched it to. This is a ready reference screening tool that Ruth can comment on further, but it's a quick pocket guide as it's called to screening for alcohol and other drug use disorders. I don't know if you want to amplify on that at all, Ruth.

Ruth Leonard: As Dan said it's a quick and easy way to take a look prior to making a referral to see if a client should be referred just by asking those questions. Are they having frequent use? Anyway, just go through the question in your mind or with the person and if so you would go ahead and make that referral. Again, we list the 800 number.

Dan: So, you know, many physicians are just not necessarily exposed to this as often, but by linking to that knowing that they are seeing a client who has some drug and alcohol or substance abuse issues that they seem to be facing they can easily just click on this even while they are in the office with the patient with the advent of the personal computers and links into exam rooms and front offices and so on. It would be a real easy way to go through that questionnaire with their patient even while they are sitting in the exam room.

The next link is a more comprehensive detail that's about a 21-page document that was developed by DASA (Division of Alcohol and Substance Abuse) and it's a primer if you will on asking, assessing, advising, assisting and arranging for substance abuse screening and treatment and there's a huge list. You can see the table of contents and Scott is just kind of running through it quickly, but very resource rich, very good primer if you just want to read one document, read that and you've got a real good comprehensive set of information regarding helping your patients.

Then going back to the web page again we'll drop down to the chronic pain agreement. We found that we've got embedded within the web page both a PDF file, which you

cannot alter of course and a WORD file. Recognizing that your client and you as a physician are engaged in such a way that you may want to get some agreement and these pain management contracts or pain agreements are the way to bridge that legal line if you will. It's a commitment document and if your patient doesn't want to commit to everything on the PDF one then take the WORD one down and create what you can get with your patient and get them to sign it and that's your commitment to each other and that's a definite good tool in terms of managing and helping that patient along. So that's embedded in the web page.

This next one is a disclosure form. As the toolkit introduces you can get the 12-month profile, SANS, the mental health and the mental health prescriptions because of the current restrictions and law. When you look at the last page of that handout I gave you you'll see an opportunity to get a full set of information on a profile. If you get this signed there's unique places for express release on HIV/AIDS, chemical dependency and so on. When they sign that document you can fax it to the lady, but my secretary is listed in that toolkit with her fax number and we'll get you the complete profile including the mental health diagnosis and any drugs that were used in treating that patient for the mental illness because with them we have to express authority and we're living within the current restrictions of state law. So that's built into the toolkit as well.

Siri Childs: May I interrupt?

Dan: Yes, Siri.

Siri Childs: Well, would this be an opportunity for Ken if he had a patient and he faxed you their release even though they are not part of the targeted review, could he receive a complete profile?

Dan: Yes, he could.

Siri Childs: There you go. We're in business right now, Ken.

Dan: There's a way to work outside of the targeted population, but we can generate that on any one that you send us that release on.

Patti Varley: Within the document, I know you were scrolling fast and stuff, is there anything specific to like adolescent drug use and street drug stuff? Or is it mainly geared at adults?

Ruth Leonard: On our web page there is information about youth treatment referrals. There's a parent guide and a companion guide for clinicians also. There is lots of information. And again I'd be willing to help with youth as well as adults.

Ken: This is Ken. I know it's kind of [inaudible] circumstances, but maybe it isn't. I guess I'm really kind of concerned with resources. I don't understand the politics of mental health and DASA in some of the funding that they do. I don't do…you don't seem to get together with regards to a co-occurring dual diagnosis type of inpatient facility, which is very…extremely [inaudible], extremely. You have got some good documentation, you've got a lot of Seattle patients, 16-bed and take 8 of that [inaudible] worse multiple hospitalizations and everything else. [inaudible] I don't really understand that, but the point I'm trying to make is when you have somebody on narcotics, alcohol for a long period of time you can almost guarantee if there's a mental disorder with that.

Patti Varley: And I would say that my experience with children has been not with all, but with several drug and alcohol treatment programs where the philosophy is no treatment. So if they are ADHD because of amphetamines seen as an abusable substance they are told they can't stay on their medication even sometimes anti-depressants. So to me that's another clinical issue in this program that I'm wondering how it's getting addressed is that relationship because our trainings in the past have been very separatist in regard to…there are still purists out there in the chemical dependency world who believe clean is clean and you're on nothing and I agree with Angelo that the recurrence of substance abuse in people who have underlying mental health disorders who aren't being treated for their mental health disorder is incredibly high and yet if I finally get a kid into treatment and that treatment protocol or belief system is to not treat their mental illness while they are getting clean and sober, it's a problem for me. So, you know, and I'm going to say this too. The resource thing is hard for me because I don't know about you, but I'm sure it's true with adults too. If I get a 17-year-old who finally is willing to go because they get to sign after age 13 whether they want to go or not, if I don't have a bed that day I'm going to tell you by tomorrow they don't want to go anymore. So those are the real life day-to-day, you know, I am certainly appreciative of this and that's why I was asking about child oriented stuff, too because I'm not a great chemical dependency expert. So any resource that can help me do a better job of that but even when I feel like I know these kids and I…those are my hurdles is in regard to the philosophies in the treatment centers, the access to those treatment centers, and I just don't if in your program this has been looked at.

Ruth Leonard: We do talk about that and on a statewide level I will say that in the last legislative session there was legislation passed moving toward more integrated services. The starting of that is the integrated screening and assessment process. So all of the chemical dependency and mental health programs are currently mandated to do a screening if you're a chemical dependency program you will also screen for mental health. If you're a mental health program you will now screen for chemical dependency and they are then charged with making those referrals and making sure there is a comprehensive treatment plan. Are we there yet? No.

Patti Varley: It's funny you bring…because my, of course, working at Children's we had our staff meeting and were shown the new form and I have to say the Sinicism was exactly what I was saying, which is, "Okay, so we're mandated to do another form, but who's going to take these kids when we make the referrals. There aren't any beds and who is going to work with us? Because a lot of them if they go in there they have to go off their mental health meds." So we did just get oriented to this and what people's attitudes were is that this is just another piece of paper that I'll get audited on as to whether I did or didn't do on a patient and I want to change that mentality, but if I can't get people…if I do a screening and I can't get a bed it's going to be a problem. Do you understand?

Ruth Leonard: I agree. Part of the issue on the medication part…a piece of it is a throwback. There are some, as you said, old timers in the field who believe you're either clean or not clean. For the youth field part of that also is the level of service. We have Level 1, which is the kids that are doing pretty well and not on meds and still in school and still living with their families and don't really have a lot of medication issues or problems within the home and then there's the Level 2 programs that really cater more to the co-occurring folks that are on medication, dropped out of school, in the legal system, have multiple problems. Those programs more clearly understand the dual diagnosis and the need to maintain medication, assess the medication, not take them off the medication. Personally I believe that's irresponsible and we are working, again,

upstream sometimes to help educate the chemical dependency treatment programs on that, but if they don't have a physician on staff sometimes it's difficult for them to maintain those medications.

Angelo Ballasiotes: You're not going to have success. [inaudible]

Ruth Leonard: I agree. We…again, we're not there, but we certainly do understand that and we are working towards that. Many days I feel like it's an uphill climb and I'm getting knocked back down to the bottom, but we are working on those issues.

Siri Childs: There is something that the DUR board could do. You could ask a question or you can send a message. So, you know, this is informational today, but you have an opportunity to let your voice be heard. So, you know, if you want to send a message, you know, through…to DASA or to mental health you can use this vehicle.

Dan: And I know both Doug Allen who heads up our DASA program, the director of DASA and Richard Kellogg, the director of our mental health division would be more than willing to hear that. If it was formal too, written too that might even help because they have to fight the uphill battle, too. Ruth eludes to one…well, they are fighting other ones and if they both joined together wouldn't that be a good…

Siri Childs: Remember…wait a minute. Remember that this reorganization has just taken place. We are all the same. We all work together. DASA, mental health and medical assistants are all one now. It falls under the umbrella of HRSA (Health Recovery and Services Administration). So your message to us right now today goes across all of those divisions, all those agencies. So I'm giving you a little bit of advice here.

Dan: A couple more pieces on the toolkit and then any other questions you may have. We are approaching about one hour so we're right on target in terms of our time.

The next area – opioid dosing guidelines you've seen but this links you to the latest set even that succeeds the snapshot we gave you earlier and that is in a final draft form. You see some things in blue demonstrating the educational pilot aspect of those guidelines. Yes, Siri?

Siri Childs: It may be wise to ask Jaymie to lead this part of the conversation.

Dan: Sure.

Jaymie: Thanks, Siri. The guidelines…actually we're in the process of formatting the guideline right now. We're thinking that it will be available March 1st. We are also working on a web site that will house the guidelines as well as the calculator as well as tools and links to various training. There are some CEs that the University of Washington is putting together, module…so it will be linked to various resources including Medicaid's toolkit as well. But we're developing that right now and hopefully we'll have everything ready to go March 1st. But it should be real soon.

Dan: Thank you, Jaymie. And then what we'll be careful to do is make sure we link to that permanent post site so that you can go back and forth as much as you need to, but that's good to hear.

Siri Childs: I want to just mention that the first version of the opioid guidelines that you saw at the last meeting has changed slightly. The formatting has changed. So, you know, you'll be particularly interested in how they have restructured it.

Dan: So that link will continue to reside in the toolkit web page and then we refer again back to the screening and referral pocket card, which we've already demonstrated. Then the next link in that new heading is our locking program or patient review and restriction. That takes you to the web page that Scott was talking about and all the richness and the latest activities there if you have questions about people qualifying, etc., etc. you can go to that and get what you need there. Again, part of this comprehensive four-fold strategy and then the last two areas are linked to the aging partners that we have. Several folks in the committee that helped to launch all of this work for our division of aging and disability services. So that's their web page. I used to work with them for about six years and recognize the unique challenges that face the aging and disabled populations and their web page is rich in all of those uniquenesses and understandings and approaches to treatment and service. So they are linked into that web page as well.

And then the last area has no live links in it, but it is a reference to the dual disorder program that we were eluding to earlier and if someone had particular questions in Yakima County…we had Ed show up to our launch and then Cindy Stevens is listed there in Clark. And then we'll add the next two when they come on board. So that gives you an orientation of the web page and it's inner activity and kind of its horsepower. I call it the liveness of it.

Then we've got a little take home message on the next to the last slide. We're trying to demonstrate to this project this integration of partnership both internally as well as externally with our community. We're trying to make sure we educate the professionals and the providers in the population that serves this targeted AOD group. We're trying to use data to identify and target the opportunity. Data driven decisions is definitely what we're trying to adhere to. We're trying to inform the clients and providers of the risks and resources as a result of this and education. We make sure the resources are know, the toolkit is out there. Collaborate outside our traditional program lines and kind of break down the silos and that last comment from Siri about letting Doug and Richard know, you know, further collaboration and teaming in this effort of screening and treatment may very well advantage all of us in the future. And then we're working with the medical community further and collaborating on the screening and treatment resources as we hopefully build that capacity within there.

Then the last slide is…can you read it? I can't. I'll go to my last page. The two-page version so we can all see it. Our next steps is to further distribute the toolkit both to providers and professionals to keep sharing the emergency room prescription and other medical history. At this point minus the mental health diagnosis and the drugs. If the state law passes that's the third bullet. We will then be able to do that slightly differently, but currently we're respecting both HIPA and Title 42 restrictions in that regard. And then continue to develop and use these guidelines for opioid dosing and work with the community to see how that kind of plays out over time.

With that we'll open up to any more questions that might be in the forefront or in the back.

Dan Lessler: I think you asked all of our questions. Thank you very much for that presentation. It was very informative.

Dan: Thank you. We did lay out more material at stations there that weren't apparently occupied, but feel free to pick those up and get them to those folks. Have anyone call us. If you have any questions on this, you know Siri's number. I know you know that.

You can give me a call directly. I'm at (360) 725-1567 and I'd be glad to answer questions or clarify things that we brought up.

Man: [inaudible]

Siri Childs: I guess before we call for an adjournment I would ask you one more time is there anything that you would like us to relay back as an unofficial recommendation or question from the DUR board?

Man: [inaudible]

[laughter]

Man: [inaudible]

Siri Childs: Pardon?

Angelo Ballasiotes: I would email too.

Siri Childs: Well, no. We really need to have it as official business conducted at this meeting, but what I've taken down is that the board recommends that we take back a message to our administrators of the mental health and the DASA program that we need to have more resources in the community for our dual diagnosis patients. Now…

Vyn Reese: Do we need to have a motion?

Man: [inaudible]

Angelo Ballasiotes: I think we're the only county that has had any new patients [inaudible]. We're the only one and we only had 16.

Siri Childs: So are you bragging or complaining? I can't tell.

Angelo Ballasiotes: Well, maybe a little bit of both. But, you know, they are backed up like two and three weeks. Now it's in shambles or we don't have the men's program now. We're robbing Paul to pay Peter. We're not as effective as we have been and we were effective.

Siri Childs: And I'm sure that what we'll hear from Doug Allen and from Richard Kellogg is that you all need to go to your legislators and demand that, you know, there's more funding for mental health and chemical dependency. But to the extent of what we can do, you know, we can certainly take this message back…

Man: …as well as outpatient services in one building in Vancouver. It was quite a model.
We took the noon hour to do a tour and just kind of see it in action and it's a relatively new effort down there to…

Man: [inaudible]

Man: No.

Man: We have an integrated type detox facility there. [inaudible] the funding to do it, but we're building…they're building another [inaudible] coed [inaudible].

Man: Thank you.

Man: Thank you very much.

Vyn Reese: Do we need to approve our minutes or are they already recorded?

Siri Childs: Actually, we do need to apparently approve the October minutes and the December minutes. Thank you for mentioning that.

Vyn Reese: If you would all take a moment to review the October and December minutes.

Jeff Graham: I think we just have the December minutes. Under the December minutes it says we did approve the October minutes with one correction.

Vyn Reese: You're right. So all we have is the December minutes. Why do we have the October minutes?

Jeff Graham: Or do we need to approve the amendment?

Siri Childs: Oh, maybe that's it. There was a correction to the October…yeah, I think it had to do with someone who was or wasn't here.

Man: Siri, do they have the ability to approve them?

Siri Childs: Did Patti have to leave too? I don't know, we've never observed a quorum rule in the past for the DUR board.

Man: Well, I'll take a motion to approve the December minutes and October minutes.

Man: I second it.

Vyn Reese: Thanks. Who made the motion?

Man: He made the motion and I seconded it.

Vyn Reese: All in favor?

Group: I.

Vyn Reese: They are approved.

Siri Childs: Thank you.